2024

Commercial FUS Manufacturers

Focused Ultrasound Foundation

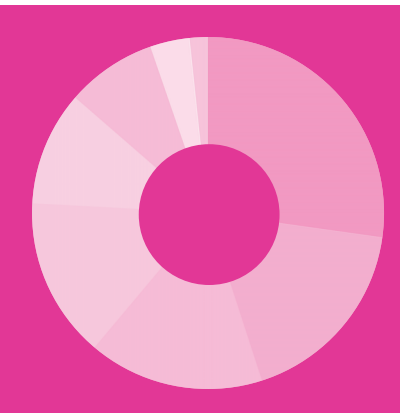
Overview

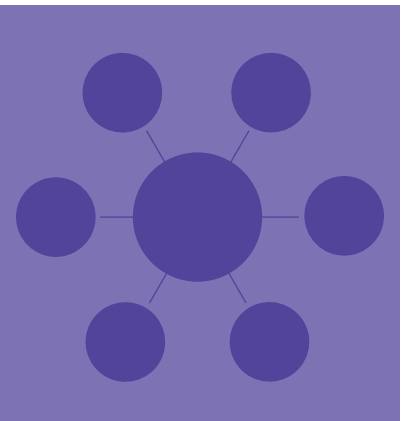
In the wake of exponential advancement, the industry has surpassed the inflection point, reflecting a shift from "if" focused ultrasound will have a critical place in the therapeutic armamentarium to "when" it will be widely available as a mainstream standard of care.

Additionally, we see increasing evidence that the field is transitioning from primarily a science-based research environment to commercialization with patient treatment spaces focused on marketing and sales. As this transition gains momentum, we want to keep pace with the data points and metrics needed to understand and evaluate this global commercialization to accurately analyze the information and disseminate our findings to all stakeholders. This chapter is a deep dive into the 17 companies with commercial products available to treat 32 indications. Information on companies still in the research and development stage can be found in Chapter 8 and/or on our website, fusfoundation.org/for-industry.

A special thank you to all the industry partners in this space who, year after year, provide information on their companies so that we can collate the data in aggregate and better understand the field.

Approvals may have changed or been updated since publication. For the most up-to-date information, please visit fusfoundation.org/the-foundation/programs/regulatory-approvals-search.





X. Commercial FUS Manufacturers

Number of Indication Approvals by Manufacturer

Manufacturer	North America	Europe	Asia	South America	Oceania	Mid East / Africa
Acoustic MedSystems[1]	1	–	–	–	–	–
Alpinion Medical Systems	–	1	2	–	–	–
Changjiangyuan Technology Development[2]	–	1	–	–	–	–
Chongqing Haifu Medical Technology	7	7	11	7	–	7 / 7
EDAP TMS	2	1	1	1	–	–
EpiSonica	–	–	1	–	–	–
EyeTechCare	–	1	1	–	–	–
HistoSonics	1	–	–	–	–	–
Insightec	8	12	14	3	11	8 / –
Profound Medical	6	7	7	5	–	3 / –
Shanghai A&S	–	1	5	–	–	–
Shende Medical[3]	–	1	–	–	–	–
Shenzhen PRO-HITU Medical	–	1	4	–	–	–
Sonablate	2	2	2	2	2	2 /
Theraclion	–	3	3	–	–	–
TOOsonix[4]	–	1	–	–	–	–
Wuxi Haiying Electronic Medical	–	–	1	–	–	–

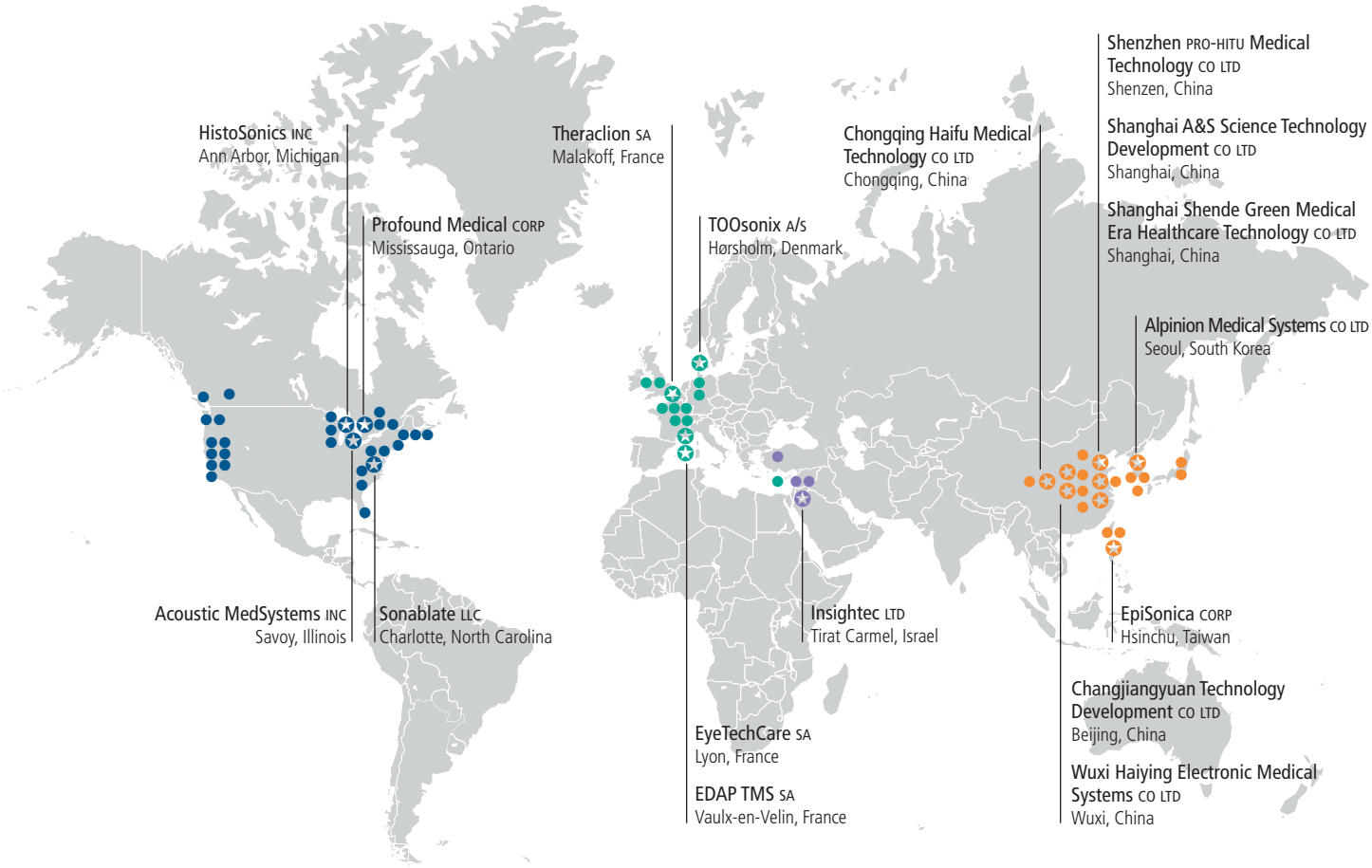
Summary of Global Approvals

42
Regulatory agencies

395
Approvals worldwide

1 Approval is for soft tissue ablation, excluding prostate.
2 Approval is for tumor ablation.
3 Manufacturer was formerly known as Shende Medical Equipment Technology.
4 Approval are for aesthetic indications, which are not tracked by the Foundation.

Clinical Device Manufacturers with Regulatory Approvals*



Clinical device manufacturers that have a device or devices with regulatory approvals by regional location.
Company listings of devices, approved indications, and regulatory agencies granting approvals are found on the subsequent pages.

Location of clinical device manufacturers without approved devices by region.

* Approvals may have changed or been updated since publication. For the most up-to-date information please visit: fusfoundation.org/the-foundation/programs/regulatory-approvals-search.

Regulatory Approvals for Companies by Region and Indication

North America

Acoustic MedSystems
- Soft tissue ablation, excluding prostate

Chongqing Haifu Medical Technology
- Bone cancer
- Breast tumors, malignant
- Kidney tumors
- Liver tumors
- Pancreatic tumors, malignant
- Uterine adenomyosis
- Uterine fibroids

EDAP TMS
- Benign prostatic hyperplasia
- Prostate cancer

HistoSonics
- Liver tumors

Insightec
- Benign prostatic hyperplasia
- Bone metastases
- Essential tremor
- Neuropathic pain
- Parkinson's disease, dyskinesia
- Parkinson's disease, tremor
- Prostate cancer
- Uterine fibroids

Profound Medical
- Benign prostatic hyperplasia
- Bone metastases
- Osteoid osteoma
- Prostate cancer
- Uterine adenomyosis
- Uterine fibroids

Sonablate
- Benign prostatic hyperplasia
- Prostate cancer

Europe

Alpinion Medical Systems
- Uterine fibroids

Changjiangyuan Technology Development
- Tumor ablation

Chongqing Haifu Medical Technology
- Bone cancer
- Breast tumors, malignant
- Kidney tumors
- Liver tumors
- Pancreatic tumors, malignant
- Uterine adenomyosis
- Uterine fibroids

EDAP TMS
- Prostate cancer

EyeTechCare
- Glaucoma

Insightec
- Arthritis, facetogenic
- Bone cancer
- Bone metastases
- Bone tumors, benign
- Essential tremor
- Multiple myeloma
- Neuropathic pain
- Parkinson's disease, dyskinesia
- Parkinson's disease, tremor
- Prostate cancer
- Uterine adenomyosis
- Uterine fibroids

Profound Medical
- Benign prostatic hyperplasia
- Bone metastases
- Desmoid tumors
- Osteoid osteoma
- Prostate cancer
- Uterine adenomyosis
- Uterine fibroids

Shanghai A&S
- Uterine fibroids

Shende Medical
- Bone metastases

Shenzhen PRO-HITU Medical
- Uterine fibroids

Sonablate
- Benign prostatic hyperplasia
- Prostate cancer

Theraclion
- Breast tumors, benign
- Thyroid nodules
- Varicose veins

TOOsonix
- Aesthetic indications

Asia

Alpinion Medical Systems
- Uterine adenomyosis
- Uterine fibroids

Chongqing Haifu Medical Technology
- Bone cancer
- Breast tumors, benign
- Breast tumors, malignant
- Cervicitis
- Kidney tumors
- Liver tumors
- Pancreatic tumors, malignant
- Rhinitis
- Soft tissue tumors, benign
- Uterine adenomyosis
- Uterine fibroids

EDAP TMS
- Prostate cancer

EpiSonica
- Soft tissue cancer

EyeTechCare
- Glaucoma

Insightec
- Arthritis, facetogenic
- Bone cancer
- Bone metastases
- Bone tumors, benign
- Depression
- Essential tremor
- Multiple myeloma
- Neuropathic pain
- Obsessive-compulsive disorder
- Parkinson's disease, dyskinesia
- Parkinson's disease, tremor
- Prostate cancer
- Uterine adenomyosis
- Uterine fibroids

Profound Medical
- Benign prostatic hyperplasia
- Bone metastases
- Desmoid tumors
- Osteoid osteoma
- Prostate cancer
- Uterine adenomyosis
- Uterine fibroids

Shanghai A&S
- Bone metastases
- Breast tumors, malignant
- Liver tumors
- Soft tissue cancer
- Uterine fibroids

Shenzhen PRO-HITU Medical
- Hyperplasia of the vulva
- Lichen sclerosis
- Uterine adenomyosis
- Uterine fibroids

Sonablate
- Benign prostatic hyperplasia
- Prostate cancer

Theraclion
- Breast tumors, benign
- Thyroid nodules
- Varicose veins

Wuxi Haiying Electronic Medical
- Uterine fibroids

Regulatory Approvals for Companies by Region and Indication continued

South America

Chongqing Haifu Medical Technology
- Bone cancer
- Breast tumors, malignant
- Kidney tumors
- Liver tumors
- Pancreatic tumors, malignant
- Uterine adenomyosis
- Uterine fibroids

EDAP TMS
- Prostate cancer

Insightec
- Essential tremor
- Neuropathic pain
- Parkinson's disease, tremor

Profound Medical
- Bone metastases
- Desmoid tumors
- Osteoid osteoma
- Uterine adenomyosis
- Uterine fibroids

Sonablate
- Benign prostatic hyperplasia
- Prostate cancer

Oceania

Insightec
- Arthritis, facetogenic
- Bone cancer
- Bone metastases
- Bone tumors, benign
- Essential tremor
- Multiple myeloma
- Neuropathic pain
- Parkinson's disease, tremor
- Prostate cancer
- Uterine adenomyosis
- Uterine fibroids

Sonablate
- Benign prostatic hyperplasia
- Prostate cancer

Middle East

Chongqing Haifu Medical Technology
- Bone cancer
- Breast tumors, malignant
- Kidney tumors
- Liver tumors
- Pancreatic tumors, malignant
- Uterine adenomyosis
- Uterine fibroids

Insightec
- Bone cancer
- Bone metastases
- Essential tremor
- Neuropathic pain
- Parkinson's disease, tremor
- Prostate cancer
- Uterine adenomyosis
- Uterine fibroids

Profound Medical
- Benign prostatic hyperplasia
- Prostate cancer
- Uterine fibroids

Sonablate
- Benign prostatic hyperplasia
- Prostate cancer

Africa

Chongqing Haifu Medical Technology
- Bone cancer
- Breast tumors, malignant
- Kidney tumors
- Liver tumors
- Pancreatic tumors, malignant
- Uterine adenomyosis
- Uterine fibroids

Clinical Device Manufacturers with Regulatory Approvals

Acoustic MedSystems INC

Devices

2	1		
Total devices	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
ACOUSTx	—	Ultrasound, CT-fluoroscopy, MRI and 3D targeting	—
TheraVision	✚	—	—

Approvals

1	1	1	1
Approved indication	**Region**	**Country**	**Total approvals***

Indication	Region	Country	Agency and date
—			
Soft tissue ablation, excluding prostate[1]	North America	United States	FDA, 2016

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.5.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

1 Approval language does not further delineate tissue type.

Clinical Device Manufacturers with Regulatory Approvals continued

Alpinion Medical Systems CO LTD

Devices

2	1		
Total devices	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
Alpius 900	✚	US guidance	—
VIFU2000	—	US guidance	—

Approvals

2	2	2	3
Approved indications	**Regions**	**Countries**	**Total approvals***

Indication	Region	Country	Agency and date
Women's health			
Uterine adenomyosis	Asia	South Korea	MFDS, 2018
Uterine fibroids	Europe Asia	Europe South Korea	CE Marking, 2016 MFDS, 2014

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.5.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

Alpinion Medical Systems CO LTD continued

Clinical research

2	1	1	2
Indications	**Region**	**Country**	**Sites**

Indication	Region	Country	Site
Gastrointestinal			
Pancreatic tumors, malignant	1	1	1
Women's health			
Uterine fibroids	1	1	1

Clinical Device Manufacturers with Regulatory Approvals continued

Changjiangyuan Technology Development CO LTD

Devices

2	2		
Total devices	**Approved devices**		

Name	Status	Treatment guidance	Planning guidance
NUTAS - Non-invasive Ultrasound Tumor Ablation System	✚	US guidance	US guidance
SUPER Knife-Focused Beam Therapy System	✚	MR & US guidance	—

Approvals

1	1	1	1
Approved indication	**Region**	**Country**	**Total approvals***

Indication	Region	Country	Agency and date
—			
Tumor ablation[1]	Europe	Europe	CE Marking, 2012
Tumor ablation[1]	Europe	Europe	CE Marking, 2018

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.5.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

1 Approval language does not specify tumor type.

Clinical Device Manufacturers with Regulatory Approvals continued

Changjiangyuan Technology Development CO LTD continued

Clinical research

1	1	1	1
Indications	**Region**	**Country**	**Sites**

Indication	Region	Country	Site
Women's health			
Breast tumors, malignant	1	1	1

Clinical Device Manufacturers with Regulatory Approvals continued

Chongqing Haifu Medical Technology CO LTD

Devices

27
Total devices

20
Approved devices

Name	Status	Treatment guidance	Planning guidance
CKC100	—	Unguided	Not used
CZB	✚	Other guidance	Other
CZF	✚	Unguided	Not used
CZF300	—	Unguided	Not used
CZG100	—	Unguided	Not used
CZG300	—	Unguided	Not used
JC	✚	US guidance	US guidance
JC-076	—	—	—
JC200	✚	US guidance	US guidance
JC200A	✚	US guidance	US guidance
JC200B	✚	US guidance	US guidance
JC200C	✚	US guidance	US guidance
JC200D	✚	US guidance	US guidance
JC200D0	✚	US guidance	US guidance
JC200D1	✚	US guidance	US guidance
JC200D2	✚	US guidance	US guidance
JC200D3	✚	US guidance	US guidance
JC210	✚	US guidance	US guidance
JC220	✚	US guidance	US guidance
JC300	✚	US guidance	US guidance
JC300P	✚	US guidance	US guidance
JC300S	✚	US guidance	US guidance

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.5.

Clinical Device Manufacturers with Regulatory Approvals continued

Chongqing Haifu Medical Technology CO LTD continued

Devices continued

Name	Status	Treatment guidance	Planning guidance
JCQ-B100	✚	US guidance	US guidance
JCQ-B130	✚	US guidance	US guidance
JCQ-B150	✚	US guidance	US guidance
LCA200	—	Unguided	Not used
LCA300	—	Unguided	Not used

Approvals

11	6	17	110
Approved indications	**Regions**	**Countries**	**Total approvals***

Indication	Region	Country	Agency and date
Gastrointestinal			
Liver tumors	North America	Mexico	COFEPRIS, 2021
	Europe	Europe	CE Marking, 2005
	Europe	Russia	Roszdravnadzor, 2007
	Asia	China	NMPA, 1999
	Asia	Hong Kong	MDD, 2019
	Asia	Indonesia	DGPMD, 2021
	Asia	Malaysia	MDA, 2017
	Asia	South Korea	MFDS, 2004
	Asia	Thailand	FDA, 2023
	South America	Colombia	INVIMA, 2015
	South America	Peru	DIGEMED, 2020
	Middle East	Saudi Arabia	SFDA, 2011
	Africa	Kenya	MOH PPB, 2023
	Africa	Nigeria	NAFDAC, 2021
	Africa	Tanzania	MOH, 2023

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.5.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

Chongqing Haifu Medical Technology CO LTD continued

Approvals continued

Indication	Region	Country	Agency and date
Gastrointestinal continued			
Pancreatic tumors, malignant	North America	Mexico	COFEPRIS, 2021
	Europe	Europe	CE Marking, 2005
	Europe	Russia	Roszdravnadzor, 2007
	Asia	Hong Kong	MDD, 2019
	Asia	Indonesia	DGPMD, 2021
	Asia	Malaysia	MDA, 2017
	Asia	Singapore	HSA, 2020
	Asia	South Korea	MFDS, 2004
	Asia	Thailand	FDA, 2023
	South America	Colombia	INVIMA, 2015
	South America	Peru	DIGEMED, 2020
	Middle East	Saudi Arabia	SFDA, 2011
	Africa	Kenya	MOH PPB, 2023
	Africa	Nigeria	NAFDAC, 2021
	Africa	Tanzania	MOH, 2023
Musculoskeletal			
Bone cancer	North America	Mexico	COFEPRIS, 2021
	Europe	Europe	CE Marking, 2005
	Europe	Russia	Roszdravnadzor, 2007
	Asia	China	NMPA, 1999
	Asia	Hong Kong	MDD, 2019
	Asia	Indonesia	DGPMD, 2021
	Asia	Malaysia	MDA, 2017
	Asia	South Korea	MFDS, 2004
	Asia	Thailand	FDA, 2023
	South America	Colombia	INVIMA, 2015
	South America	Peru	DIGEMED, 2020
	Middle East	Saudi Arabia	SFDA, 2011
	Africa	Kenya	MOH PPB, 2023
	Africa	Nigeria	NAFDAC, 2021
	Africa	Tanzania	MOH, 2023

Clinical Device Manufacturers with Regulatory Approvals continued

Chongqing Haifu Medical Technology CO LTD continued

Approvals continued

Indication	Region	Country	Agency and date
Musculoskeletal continued			
Soft tissue tumors, benign	Asia	China	NMPA, 1999
Pulmonary			
Rhinitis	Asia	China	NMPA, 1999
Urological			
Kidney tumors	North America	Mexico	COFEPRIS, 2021
	Europe	Europe	CE Marking, 2005
	Europe	Russia	Roszdravnadzor, 2007
	Asia	Hong Kong	MDD, 2019
	Asia	Indonesia	DGPMD, 2021
	Asia	Malaysia	MDA, 2017
	Asia	South Korea	MFDS, 2004
	Asia	Thailand	FDA, 2023
	South America	Colombia	INVIMA, 2015
	South America	Peru	DIGEMED, 2020
	Middle East	Saudi Arabia	SFDA, 2011
	Africa	Kenya	MOH PPB, 2023
	Africa	Nigeria	NAFDAC, 2021
	Africa	Tanzania	MOH, 2023

Clinical Device Manufacturers with Regulatory Approvals continued

Chongqing Haifu Medical Technology CO LTD continued

Approvals continued

Indication	Region	Country	Agency and date
Women's health			
Breast tumors, benign	Asia	China	NMPA, 1999
Breast tumors, malignant	North America	Mexico	COFEPRIS, 2021
	Europe	Europe	CE Marking, 2005
	Europe	Russia	Roszdravnadzor, 2007
	Asia	China	NMPA, 1999
	Asia	Hong Kong	MDD, 2019
	Asia	Indonesia	DGPMD, 2021
	Asia	Malaysia	MDA, 2017
	Asia	South Korea	MFDS, 2004
	Asia	Thailand	FDA, 2023
	South America	Colombia	INVIMA, 2015
	South America	Peru	DIGEMED, 2020
	Middle East	Saudi Arabia	SFDA, 2011
	Africa	Kenya	MOH PPB, 2023
	Africa	Nigeria	NAFDAC, 2021
	Africa	Tanzania	MOH, 2023
Cervicitis	Asia	China	NMPA, 1999
Uterine adenomyosis	North America	Mexico	COFEPRIS, 2021
	Europe	Europe	CE Marking, 2005
	Europe	Russia	Roszdravnadzor, 2007
	Asia	Hong Kong	MDD, 2019
	Asia	Indonesia	DGPMD, 2021
	Asia	Malaysia	MDA, 2017
	Asia	Singapore	HSA, 2020
	Asia	South Korea	MFDS, 2004
	Asia	Thailand	FDA, 2023
	South America	Colombia	INVIMA, 2015
	South America	Peru	DIGEMED, 2020
	Middle East	Saudi Arabia	SFDA, 2011

Clinical Device Manufacturers with Regulatory Approvals continued

Chongqing Haifu Medical Technology CO LTD continued

Approvals continued

Indication	Region	Country	Agency and date
Women's health continued			
Uterine adenomyosis, continued	Africa	Kenya	MOH PPB, 2023
	Africa	Nigeria	NAFDAC, 2021
	Africa	Tanzania	MOH, 2023
Uterine fibroids	North America	Mexico	COFEPRIS, 2021
	Europe	Europe	CE Marking, 2005
	Europe	Russia	Roszdravnadzor, 2007
	Asia	China	NMPA, 1999
	Asia	Hong Kong	MDD, 2019
	Asia	Indonesia	DGPMD, 2021
	Asia	Malaysia	MDA, 2017
	Asia	Singapore	HSA, 2020
	Asia	South Korea	MFDS, 2004
	Asia	Taiwan	FDA, 2012
	Asia	Thailand	FDA, 2023
	South America	Colombia	INVIMA, 2015
	South America	Peru	DIGEMED, 2020
	Middle East	Saudi Arabia	SFDA, 2011
	Africa	Kenya	MOH PPB, 2023
	Africa	Nigeria	NAFDAC, 2021
	Africa	Tanzania	MOH, 2023

Clinical Device Manufacturers with Regulatory Approvals continued

Chongqing Haifu Medical Technology CO LTD continued

Clinical research

11 Indications	2 Regions	6 Countries	8 Sites

Indication	Region	Country	Site
Gastrointestinal			
Liver tumors	2	4	4
Pancreatic tumors	1	1	1
Pancreatic tumors, malignant	1	3	3
Musculoskeletal			
Osteoid osteoma	1	1	1
Sacral chordoma	1	1	1
Soft tissue cancer	1	1	1
Soft tissue tumors, benign	1	3	3
Urological			
Kidney tumors	1	2	2
Women's health			
Breast tumors, malignant	1	2	2
Uterine adenomyosis	1	2	2
Uterine fibroids	2	3	4

Clinical Device Manufacturers with Regulatory Approvals continued

Chongqing Haifu Medical Technology CO LTD continued

> **Chongqing Haifu**, founded in 1999, is devoted to the development, manufacturing, and sales of HIFU systems to treat solid tumors, with a total number of treated cases reaching more than 240,000 in 2023."
>
> — Chongqing Haifu Medical Technology CO LTD

Clinical Device Manufacturers with Regulatory Approvals continued

EDAP TMS SA

Devices

4 Total devices

2 Approved devices

Name	Status	Treatment guidance	Planning guidance
Ablatherm	✚	Image fusion	US guidance
EDAP (Prototype)	—	US guidance	US guidance
Focal One	✚	Image fusion	MR guidance, US guidance, biopsies
Mfocus	—	US guidance	US guidance

Approvals

2 Approved indications

4 Regions

6 Countries

12 Total approvals*

Indication	Region	Country	Agency and date
Urological			
Benign prostatic hyperplasia	North America	United States	FDA, 2015
Prostate cancer	North America	Canada	Health Canada, 2003
	North America	United States	FDA, 2015
	Europe	Europe	CE Marking, 2013
	Europe	Russia	Roszdravnadzor, 2002
	Asia	South Korea	MFDS, 2002
	South America	Brazil	ANVISA, 2016

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.5.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

EDAP TMS SA continued

Clinical research

4	2	6	34
Indications	**Regions**	**Countries**	**Sites**

Indication	Region	Country	Site
Urological			
Benign prostatic hyperplasia	1	1	1
Prostate cancer	2	6	27
Women's health			
Endometriosis	1	1	1
Endometriosis, colorectal	1	1	9

> **EDAP TMS** designs, produces, and markets medical equipment dedicated to minimally invasive therapies based on robotic therapeutic ultrasound. Our lead product, Focal One®, combines the latest technologies in imaging and treatment modalities in urology and gynecology."
>
> — EDAP TMS SA

Clinical Device Manufacturers with Regulatory Approvals continued

EpiSonica CORP

Devices

1	1		
Total device	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
ArcBLATE (ARC-100M)	✚	MR guidance	MR guidance

Approvals

1	1	1	1
Approved indication	**Region**	**Country**	**Total approvals***

Indication	Region	Country	Agency and date
Musculoskeletal			
Soft tissue cancer	Asia	Taiwan	FDA, 2016

> **EpiSonica Corp** is a leading company that is focusing on development of supine and prone MRgHIFU systems. Our ArcBlate system provides treatment for uterine fibroids and uterine adenomyosis disease as well as the application of pain palliation for bone metastases."
>
> — EpiSonica CORP

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.5.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

EyeTechCare SA

Devices

1	1		
Total device	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
EyeOP1	✚	Unguided	—

Approvals

1	2	2	2
Approved indication	**Regions**	**Countries**	**Total approvals***

Indication	Region	Country	Agency and date
Ophthalmological			
Glaucoma	Europe	Europe	CE Marking, 2011
	Asia	China	NMPA, 2017

Clinical research

1	2	2	2
Indication	**Regions**	**Countries**	**Sites**

Indication	Region	Country	Site
Ophthalmological			
Glaucoma	2	2	2

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.5.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

HistoSonics INC

Devices

1	1		
Total device	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
Edison	✚	US guidance	US guidance

Approvals

1	1	1	1
Approved indication	**Region**	**Country**	**Total approvals***

Indication	Region	Country	Agency and date
Gastrointestinal			
Liver tumors	North America	United States	FDA, 2023

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.5.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

HistoSonics INC continued

Clinical research

2 Indications	2 Regions	5 Countries	16 Sites

Indication	Region	Country	Site
Gastrointestinal			
Liver tumors	2	5	13
Urological			
Kidney tumors	2	2	4

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD

Devices

3	3		
Total devices	**Approved devices**		

Name	Status	Treatment guidance	Planning guidance
Exablate Body	✚	MR guidance	MR guidance
Exablate Neuro	✚	MR guidance	MR/CT guidance
Exablate Prostate	✚	MR guidance	MR guidance

Approvals

15	6	30	141
Approved indications	**Regions**	**Countries**	**Total approvals***

Indication	Region	Country	Agency and date
Musculoskeletal			
Arthritis, facetogenic	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2017
	Asia	Kazakhstan	NCEM, 2019
	Asia	South Korea	MFDS, 2015
	Asia	Thailand	FDA, 2020
	Oceania	New Zealand	MEDSAFE, 2006
Bone cancer	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2017
	Asia	Kazakhstan	NCEM, 2019
	Asia	Thailand	FDA, 2020
	Oceania	New Zealand	MEDSAFE, 2006
	Middle East	Israel	AMAR, 2008

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.5.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD continued

Approvals continued

Indication	Region	Country	Agency and date
Musculoskeletal continued			
Bone metastases	North America	Canada	Health Canada, 2013
	North America	United States	FDA, 2012
	Europe	Belarus	MOH, 2021
	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2017
	Asia	Kazakhstan	NCEM, 2019
	Asia	South Korea	MFDS, 2015
	Asia	Thailand	FDA, 2020
	Oceania	New Zealand	MEDSAFE, 2006
	Middle East	Kuwait	MOH FDCD, 2021
	Middle East	Saudi Arabia	SFDA, 2021
Bone tumors, benign	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2017
	Asia	Kazakhstan	NCEM, 2019
	Asia	Thailand	FDA, 2020
	Oceania	New Zealand	MEDSAFE, 2006
Multiple myeloma	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2017
	Asia	Kazakhstan	NCEM, 2019
	Asia	Thailand	FDA, 2020
	Oceania	New Zealand	MEDSAFE, 2006

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD continued

Approvals continued

Indication	Region	Country	Agency and date
Neurological			
Depression	Asia	South Korea	MFDS, 2015
Essential tremor	North America	Canada	Health Canada, 2016
	North America	Mexico	COFEPRIS, 2023
	North America	United States	FDA, 2016
	Europe	Europe	CE Marking, 2012
	Europe	Russia	Roszdravnadzor, 2017
	Europe	Switzerland	Swissmedic, 2022
	Europe	United Kingdom	MHRA, 2022
	Asia	China	NMPA, 2021
	Asia	Hong Kong	MDD, 2020
	Asia	India	CDSCO, 2021
	Asia	Japan	MHLW, 2016
	Asia	Kazakhstan	NCEM, 2020
	Asia	Philippines	FDA, 2018
	Asia	Singapore	HSA, 2021
	Asia	South Korea	MFDS, 2015
	Asia	Taiwan	FDA, 2017
	Asia	Thailand	FDA, 2020
	South America	Argentina	ANMAT, 2019
	South America	Brazil	ANVISA, 2020
	South America	Chile	ANAMED, 2018
	South America	Colombia	INVIMA, 2021
	South America	Peru	DIGEMED, 2021
	Oceania	Australia	TGA, 2015
	Middle East	Israel	AMAR, 2015
	Middle East	Turkey	TITUBB, 2017
	Middle East	United Arab Emirates	MOHAP, 2022

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD continued

Approvals continued

Indication	Region	Country	Agency and date
Neurological continued			
Neuropathic pain	North America	Mexico	COFEPRIS, 2023
	Europe	Europe	CE Marking, 2012
	Europe	Russia	Roszdravnadzor, 2017
	Europe	Switzerland	Swissmedic, 2022
	Europe	United Kingdom	MHRA, 2022
	Asia	Hong Kong	MDD, 2020
	Asia	India	CDSCO, 2021
	Asia	Kazakhstan	NCEM, 2020
	Asia	Philippines	FDA, 2018
	Asia	South Korea	MFDS, 2015
	Asia	Thailand	FDA, 2020
	South America	Argentina	ANMAT, 2019
	South America	Brazil	ANVISA, 2020
	South America	Chile	ANAMED, 2018
	South America	Colombia	INVIMA, 2021
	South America	Peru	DIGEMED, 2021
	Oceania	Australia	TGA, 2015
	Middle East	Israel	AMAR, 2015
	Middle East	Turkey	TITUBB, 2017
	Middle East	United Arab Emirates	MOHAP, 2022
Obsessive-compulsive disorder	Asia	South Korea	MFDS, 2015
Parkinson's disease, dyskinesia	North America	United States	FDA, 2021
	Europe	Russia	Roszdravnadzor, 2017
	Asia	Japan	MHLW, 2020
	Asia	South Korea	MFDS, 2015

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD continued

Approvals continued

Indication	Region	Country	Agency and date
Neurological continued			
Parkinson's disease, tremor	North America	Mexico	COFEPRIS, 2023
	North America	United States	FDA, 2018
	Europe	Europe	CE Marking, 2012
	Europe	Russia	Roszdravnadzor, 2017
	Europe	Switzerland	Swissmedic, 2022
	Europe	United Kingdom	MHRA, 2022
	Asia	China	NMPA, 2021
	Asia	Hong Kong	MDD, 2020
	Asia	India	CDSCO, 2021
	Asia	Japan	MHLW, 2020
	Asia	Kazakhstan	NCEM, 2020
	Asia	Philippines	FDA, 2018
	Asia	Singapore	HSA, 2021
	Asia	South Korea	MFDS, 2015
	Asia	Taiwan	FDA, 2022
	Asia	Thailand	FDA, 2020
	South America	Argentina	ANMAT, 2019
	South America	Brazil	ANVISA, 2020
	South America	Chile	ANAMED, 2018
	South America	Colombia	INVIMA, 2021
	South America	Peru	DIGEMED, 2021
	Oceania	Australia	TGA, 2015
	Middle East	Israel	AMAR, 2015
	Middle East	Turkey	TITUBB, 2017
	Middle East	United Arab Emirates	MOHAP, 2022

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD continued

Approvals continued

Indication	Region	Country	Agency and date
Urological			
Benign prostatic hyperplasia	North America	United States	FDA, 2021
Prostate cancer	North America	United States	FDA, 2021
	Europe	Belarus	MOH, 2021
	Europe	Europe	CE Marking, 2016
	Europe	Russia	Roszdravnadzor, 2017
	Asia	Kazakhstan	NCEM, 2019
	Asia	Thailand	FDA, 2020
	Oceania	Australia	TGA, 2016
	Oceania	New Zealand	MEDSAFE, 2016
	Middle East	Israel	AMAR, 2022
Women's health			
Uterine adenomyosis	Europe	Europe	CE Marking, 2006
	Asia	Kazakhstan	NCEM, 2019
	Asia	Thailand	FDA, 2020
	Oceania	New Zealand	MEDSAFE, 2006
	Middle East	Israel	AMAR, 2008
Uterine fibroids	North America	Canada	Health Canada, 2013
	North America	United States	FDA, 2004
	Europe	Belarus	MOH, 2021
	Europe	Europe	CE Marking, 2006
	Europe	Russia	Roszdravnadzor, 2006
	Asia	China	NMPA, 2013
	Asia	Japan	MHLW, 2006
	Asia	Kazakhstan	NCEM, 2019
	Asia	Singapore	HSA, 2012
	Asia	South Korea	MFDS, 2011
	Asia	Taiwan	FDA, 2006
	Asia	Thailand	FDA, 2020
	Oceania	New Zealand	MEDSAFE, 2006

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD continued

Approvals continued

Indication	Region	Country	Agency and date
Women's health continued			
Uterine fibroids continued	Middle East	Israel	AMAR, 2003
	Middle East	Kuwait	MOH FDCD, 2021
	Middle East	Saudi Arabia	SFDA, 2021

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD continued

Clinical research

41	5	17	84
Indications	**Regions**	**Countries**	**Sites**

Indication	Region	Country	Site
Gastrointestinal			
Liver tumors	1	1	2
Pancreatic tumors, malignant	1	1	1
Miscellaneous			
Head & neck tumors	1	2	2
Musculoskeletal			
Arthritis, facetogenic	2	5	6
Arthritis, knee	1	1	1
Bone cancer	1	1	2
Bone metastases	4	7	9
Bone tumors, benign	1	1	1
Osteoid osteoma	2	3	5
Soft tissue cancer	2	2	2
Soft tissue tumors, benign	2	2	2
Neurological			
Alzheimer's disease	2	3	12
Amyotrophic lateral sclerosis	1	1	1
Astrocytoma	1	1	2
Brain metastases, breast cancer	1	1	1
Brain metastases, lung cancer	1	2	5
Brain metastases, melanoma	1	1	1

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD continued

Clinical research continued

Indication	Region	Country	Site
Neurological continued			
Brain tumors, general	1	2	2
Cancer pain	1	1	1
Depression	2	2	2
Dystonia	1	3	4
Dystonia, hand	1	1	1
Epilepsy	2	3	9
Essential tremor	4	11	17
Glioblastoma	4	6	22
Neurofibromatosis	1	1	1
Neuropathic pain	1	1	1
Obsessive-compulsive disorder	1	1	2
Opioid and other addictions	1	1	1
Painful amputation neuromas	1	1	1
Parkinson's disease, dyskinesia	2	2	8
Parkinson's disease, tremor	3	8	12
Parkinson's disease, underlying cause	1	2	2
Pontine glioma	1	2	5
Tremor, orthostatic	1	1	1
Trigeminal neuralgia	1	1	1

Clinical Device Manufacturers with Regulatory Approvals continued

Insightec LTD continued

Clinical research continued

Indication	Region	Country	Site
Urological			
Prostate cancer	2	2	5
Women's health			
Endometriosis	1	1	1
Uterine adenomyosis	3	4	5
Uterine fibroids	4	11	15

> **Insightec** is a global healthcare company creating the next generation of patient care by realizing the therapeutic power of acoustic energy. Insightec is dedicated to the research and commercial application of focused ultrasound in multiple indications."
>
> — Insightec INC

Clinical Device Manufacturers with Regulatory Approvals continued

Profound Medical CORP

Devices

2	2		
Total devices	**Approved devices**		

Name	Status	Treatment guidance	Planning guidance
Sonalleve	✚	MR guidance	MR guidance
TULSA-PRO	✚	MR guidance	MR guidance

Approvals[1]

7	5	13	51
Approved indications	**Regions**	**Countries**	**Total approvals***

Indication	Region	Country	Agency and date
Musculoskeletal			
Bone metastases	North America	Mexico	COFEPRIS, 2018
	Europe	Europe	CE Marking, 2011
	Asia	Malaysia	MDA, 2015
	Asia	Philippines	FDA, 2013
	Asia	Singapore	HSA, 2021
	Asia	Thailand	FDA, 2023
	Asia	Vietnam	DMEW, 2010
	South America	Argentina	ANMAT, 2012
Desmoid tumors	Europe	Europe	CE Marking, 2021
	Asia	Thailand	FDA, 2023
	South America	Argentina	ANMAT, 2022

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.5.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

Profound Medical CORP continued

Approvals continued

Indication	Region	Country	Agency and date
Musculoskeletal continued			
Osteoid osteoma	North America	United States	FDA, 2020
	Europe	Europe	CE Marking, 2020
	Asia	Singapore	HSA, 2021
	Asia	Thailand	FDA, 2023
	South America	Argentina	ANMAT, 2022
Urological			
Benign prostatic hyperplasia	North America	Canada	Health Canada, 2019
	North America	United States	FDA, 2019
	Europe	Europe	CE Marking, 2016
	Asia	Malaysia	MDA, 2023
	Asia	Philippines	FDA, 2023
	Asia	Singapore	HSA, 2019
	Asia	Thailand	FDA, 2023
	Middle East	Saudi Arabia	SFDA, 2018
Prostate cancer	North America	Canada	Health Canada, 2019
	North America	United States	FDA, 2019
	Europe	Europe	CE Marking, 2016
	Asia	Malaysia	MDA, 2023
	Asia	Philippines	FDA, 2023
	Asia	Singapore	HSA, 2019
	Asia	Thailand	FDA, 2023
	Middle East	Saudi Arabia	SFDA, 2018

Clinical Device Manufacturers with Regulatory Approvals continued

Profound Medical CORP continued

Approvals continued

Indication	Region	Country	Agency and date
Women's health			
Uterine adenomyosis	North America	Mexico	COFEPRIS, 2018
	Europe	Europe	CE Marking, 2010
	Asia	Malaysia	MDA, 2015
	Asia	Philippines	FDA, 2023
	Asia	Singapore	HSA, 2021
	Asia	Thailand	FDA, 2023
	Asia	Vietnam	DMEW, 2010
	South America	Argentina	ANMAT, 2012
Uterine fibroids	North America	Canada	Health Canada, 2013
	Europe	Europe	CE Marking, 2009
	Asia	China	NMPA, 2018
	Asia	Malaysia	MDA, 2015
	Asia	Philippines	FDA, 2023
	Asia	Singapore	HSA, 2021
	Asia	South Korea	MFDS, 2012
	Asia	Thailand	FDA, 2023
	Asia	Vietnam	DMEW, 2010
	South America	Argentina	ANMAT, 2012
	Middle East	Saudi Arabia	SFDA, 2015

Clinical Device Manufacturers with Regulatory Approvals continued

Profound Medical CORP continued

Clinical research

23	3	10	30
Indications	**Regions**	**Countries**	**Sites**

Indication	Region	Country	Site
Cardiovascular			
Arteriovenous malformations	1	1	1
Gastrointestinal			
Liver tumors	1	1	1
Pancreatic tumors	1	1	1
Pancreatic tumors, malignant	1	1	1
Miscellaneous			
Head & neck tumors	1	1	1
Melanoma	1	1	1
Multiple tumors[1]	1	1	1
Musculoskeletal			
Arthritis, facetogenic	1	1	1
Arthritis, sacroiliac	1	1	1
Bone cancer	2	3	4
Bone metastases	2	5	6
Bone tumors, benign	1	2	2
Desmoid tumors	1	3	4
Osteoid osteoma	2	2	2
Plantar fasciitis	1	1	1
Soft tissue cancer	2	4	4
Soft tissue tumors, benign	2	2	2

1 Protocols inclusive of more than one indication

Clinical Device Manufacturers with Regulatory Approvals continued

Profound Medical CORP continued

Clinical research continued

Indication	Region	Country	Site
Urological			
Benign prostatic hyperplasia	1	1	1
Prostate cancer	2	6	20
Women's health			
Breast tumors, malignant	2	2	2
Uterine adenomyosis	2	3	3
Uterine fibroids	2	5	7
Vaginal tumors	1	1	1

1 Protocols inclusive of more than one indication

Clinical Device Manufacturers with Regulatory Approvals continued

Profound Medical CORP continued

> **Profound Medical** develops customizable, incision-free ablative therapies which combine real-time MRI, thermal ultrasound, autonomous robotics, and closed-loop process control to change the standard of care for physicians and patients."
>
> — Profound Medical CORP

Clinical Device Manufacturers with Regulatory Approvals continued

Shanghai A&S Science Technology Development CO, LTD

Devices

1	1		
Total device	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
HIFUNIT9000	✚	US guidance	MR guidance

Approvals

5	2	4	8
Approved indications	**Regions**	**Countries**	**Total approvals***

Indication	Region	Country	Agency and date
Gastrointestinal			
Liver tumors	Asia	China	NMPA, 2002
Musculoskeletal			
Bone metastases	Asia	China	NMPA, 2002
Soft tissue cancer	Asia	China	NMPA, 2002
Women's health			
Breast tumors, malignant	Asia	China	NMPA, 2002
Uterine fibroids	Europe	Europe	CE Marking, 2008
	Asia	China	NMPA, 2002
	Asia	South Korea	MFDS, 2007
	Asia	Thailand	FDA, 2013

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.5.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

Shanghai A&S Science Technology Development CO, LTD continued

Clinical research

1 Indication	1 Region	1 Country	1 Site

Indication	Region	Country	Site
Gastrointestinal			
Liver tumors	1	1	1

> **Shanghai A&S Science Technology Development** is a leading company focused on high intensity focused ultrasound for tumor ablation with ultrasound guidance. Based in Shanghai, A&S has expanded business in Asia with over 200 installations."
>
> — Shanghai A&S Science Technology Development CO LTD

Clinical Device Manufacturers with Regulatory Approvals continued

Shanghai Shende Green Medical Era Healthcare Technology CO LTD[1]

Devices

3	1		
Total device	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
Aceso-NIA	—	MR guidance	MR/CT guidance
Aceso-PIA	—	MR guidance	MR guidance
Aceso-UIA	✚	MR guidance	MR guidance

Approvals

1	1	1	1
Approved indication	**Region**	**Country**	**Total approvals***

Indication	Region	Country	Agency and date
Musculoskeletal			
Bone metastases	Europe	Europe	CE Marking, 2020

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.5.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

1 Manufacturer was formerly known as Shende Medical Equipment Technology.

Clinical Device Manufacturers with Regulatory Approvals continued

Shanghai Shende Green Medical Era Healthcare Technology CO LTD continued

Clinical research

3	1	1	7
Indications	**Region**	**Country**	**Sites**

Indication	Region	Country	Site
Musculoskeletal			
Bone metastases	1	1	3
Women's health			
Uterine adenomyosis	1	1	6
Uterine fibroids	1	1	5

> **Shende Green Medical Era** was established in 2013 and is dedicated to the technical breakthrough and productization of MR-guided phased HIFU. The company focuses on the noninvasive treatment of solid tumors and diseases of the nervous system."
>
> — Shanghai Shende Green Medical Era Healthcare Technology CO LTD

Clinical Device Manufacturers with Regulatory Approvals continued

Shenzhen PRO-HITU Medical Technology CO, LTD

Devices

5 Total devices

3 Approved devices

Name	Status	Treatment guidance	Planning guidance
PRO2008	✚	US guidance	US guidance
PRO300	✚	US guidance	US guidance
PRO3008	—	US guidance	US guidance
PRO5G	✚	Other guidance	Visual guidance
UT1000	—	Unguided	Not used

Approvals

4 Approved indications

2 Regions

4 Countries

10 Total approvals*

Indication	Region	Country	Agency and date
Women's health			
Hyperplasia of the vulva	Asia	China	NMPA, 2019
Lichen sclerosis	Asia	China	NMPA, 2019
Uterine adenomyosis	Asia	South Korea	MFDS, 2016
Uterine fibroids	Europe Asia Asia	Europe China Taiwan	CE Marking, 2012 MDA, 2012 FDA, 2018

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.5.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

Shenzhen PRO-HITU Medical Technology CO, LTD continued

Clinical research

2	1	1	4
Indications	**Region**	**Country**	**Sites**

Indication	Region	Country	Site
Women's health			
Uterine adenomyosis	1	1	3
Uterine fibroids	1	1	3

> **Shenzen PRO–HITU Medical Technology** was established in 2003, focusing on R&D of large ultrasonic treatment equipment. Vision: The pioneering of noninvasive therapy. Mission: Respect life in therapy."
>
> — Shenzen PRO-HITU Medical CO, LTD

Clinical Device Manufacturers with Regulatory Approvals continued

Sonablate CORP

Devices

2	2		
Total devices	**Approved devices**		

Name	Status	Treatment guidance	Planning guidance
Sonablate	✚	US guidance	MR/US fusion
Sonatherm	✚	US guidance	US guidance

Approvals

2	6	22	41
Approved indications	**Regions**	**Countries**	**Total approvals***

Indication	Region	Country	Agency and date
Urological			
Benign prostatic hyperplasia	North America	Canada	Health Canada, 2005
	North America	Costa Rica	Ministerio de Salud, 2005
	North America	Dominican Republic	MISPAS, 2005
	North America	United States	FDA, 2006
	Europe	Europe	CE Marking, 2001
	Europe	Russia	Roszdravnadzor, 2005
	Europe	United Kingdom	MHRA, 2019
	Asia	China	NMPA, 2022
	Asia	Hong Kong	MDD, 2018
	Asia	India	CDSCO, 2011
	Asia	Japan	MHLW, 2001
	Asia	Macau	ISAF, 2020
	Asia	Malaysia	MDA, 2021
	Asia	South Korea	MFDS, 2016

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.5.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

Sonablate CORP continued

Approvals continued

Indication	Region	Country	Agency and date
Urological continued			
Benign prostatic hyperplasia con't.	South America	Argentina	ANMAT, 2006
	South America	Colombia	INVIMA, 2015
	South America	Ecuador	ANRCVS, 2011
	South America	Trinidad and Tobago	Ministry of Health, 2012
	Oceania	Australia	TGA, 2005
	Middle East	United Arab Emirates	MOHAP, 2022
Prostate cancer	North America	Bahamas	Ministry of Health, 2007
	North America	Canada	Health Canada, 2005
	North America	Costa Rica	Ministerio de Salud, 2005
	North America	Dominican Republic	MISPAS, 2005
	North America	United States	FDA, 2006
	Europe	Europe	CE Marking, 2001
	Europe	Russia	Roszdravnadzor, 2005
	Europe	United Kingdom	MHRA, 2019
	Asia	China	NMPA, 2020
	Asia	Hong Kong	MDD, 2018
	Asia	India	CDSCO, 2011
	Asia	Macau	ISAF, 2020
	Asia	Malaysia	MDA, 2021
	Asia	South Korea	MFDS, 2016
	Asia	Taiwan	FDA, 2020
	South America	Argentina	ANMAT, 2006
	South America	Colombia	INVIMA, 2015
	South America	Ecuador	ANRCVS, 2011
	South America	Trinidad and Tobago	Ministry of Health, 2012
	Oceania	Australia	TGA, 2005
	Middle East	United Arab Emirates	MOHAP, 2022

Clinical Device Manufacturers with Regulatory Approvals continued

Sonablate CORP continued

Clinical research

6	3	5	14
Indications	**Regions**	**Countries**	**Sites**

Indication	Region	Country	Site
Gastrointestinal			
Colorectal tumors	1	1	2
Urological			
Prostate cancer	3	5	14
Women's health			
Cervical tumors	1	1	2
Endometrial tumors	1	1	1
Ovarian tumors	1	1	1
Vaginal tumors	1	1	1

> **Sonablate** is a world leader in minimally invasive focused ultrasound technologies. Sonablate Corp. is committed to developing focused ultrasound related technologies that support precise and innovative medical procedures."
>
> — Sonablate CORP

Clinical Device Manufacturers with Regulatory Approvals continued

Theraclion SA

Devices

2	2		
Total devices	**Approved devices**		

Name	Status	Treatment guidance	Planning guidance
Echopulse	✚	US guidance	US guidance
SONOVEIN	✚	US guidance	Not used

Approvals

3	2	8	19
Approved indications	**Regions**	**Countries**	**Total approvals***

Indication	Region	Country	Agency and date
Cardiovascular			
Varicose veins	Europe	Europe	CE Marking, 2019
	Asia	Hong Kong	MDD, 2021
	Asia	Singapore	HSA, 2019
Endocrine disorders			
Thyroid nodules	Europe	Europe	CE Marking, 2007
	Europe	Russia	Roszdravnadzor, 2017
	Asia	Hong Kong	MDD, 2007
	Asia	Malaysia	MDA, 2019
	Asia	Singapore	HSA, 2016
	Asia	South Korea	MFDS, 2017
	Asia	Taiwan	FDA, 2019
	Asia	Thailand	FDA, 2019

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.5.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Clinical Device Manufacturers with Regulatory Approvals continued

Theraclion SA continued

Approvals continued

Indication	Region	Country	Agency and date
Women's health			
Breast tumors, benign	Europe	Europe	CE Marking, 2012
	Europe	Russia	Roszdravnadzor, 2017
	Asia	Hong Kong	MDD, 2012
	Asia	Malaysia	MDA, 2019
	Asia	Singapore	HSA, 2016
	Asia	South Korea	MFDS, 2017
	Asia	Taiwan	FDA, 2018
	Asia	Thailand	FDA, 2019

Clinical research

11	2	4	9
Indications	**Regions**	**Countries**	**Sites**

Indication	Region	Country	Site
Cardiovascular			
Varicose veins	2	4	5
Gastrointestinal			
Esophageal tumors	1	1	1
Gastric tumors	1	1	1
Miscellaneous			
Melanoma	1	1	1
Multiple tumors[1]	1	1	1

1 Protocols inclusive of more than one indication

Clinical Device Manufacturers with Regulatory Approvals continued

Theraclion SA continued

Clinical research continued

Indication	Region	Country	Site
Pulmonary			
Lung cancer	1	1	1
Urological			
Prostate cancer	1	1	1
Women's health			
Breast tumors, benign	1	1	3
Breast tumors, malignant	1	1	1
Cervical tumors	1	1	1
Ovarian tumors	1	1	1

> **Theraclion** is a French MedTech company developing robotic platforms treating extracorporeally through the innovative use of High Intensity Focused Ultrasound (HIFU): SONOVEIN® for varicose veins and Echopulse® for breast fibroadenoma and thyroid nodules."
>
> — Theraclion SA

Clinical Device Manufacturers with Regulatory Approvals continued

Theraclion SA - Veterinary Medicine

Devices

1	1		
Total device	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
Echopulse	✚[1]	US guidance	US guidance

Clinical research

1	1	1	1
Indication	**Region**	**Country**	**Site**

Indication	Region	Country	Site
Feline			
Soft tissue cancer	1	1	1

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.5. .

1 Veterinary devices are not subject to regulatory review.

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Clinical Device Manufacturers with Regulatory Approvals continued

TOOsonix A/S

Devices

2	1		
Total devices	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
System ONE-M	✚	Image fusion	Visual guidance
System ONE-R	—	Image fusion	Visual guidance

Approvals

0	1	1	0
Approved indications[1]	**Region**	**Country**	**Total approvals***[1]

Indication	Region	Country	Agency and date
—	Europe	Europe	CE Marking, 2020

✚ Devices with regulatory approvals.
Companies in this section can have approval for more than one indication from a given regulatory agency. To see a breakdown of the regional approvals, indications, and timelines, see charts starting on p. IX.5.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

1 This device is currently approved for aesthetic indications, which are not tracked by the Foundation.

Clinical Device Manufacturers with Regulatory Approvals continued

TOOsonix s/A continued

Clinical research

4 Indications	2 Regions	4 Countries	5 Sites

Indication	Region	Country	Site
Miscellaneous			
Actinic keratosis	1	2	2
Basal cell carcinoma	1	2	3
Kaposi's sarcoma	1	1	1
Neurological			
Neurofibromatosis	1	1	1

> **TOOsonix** is a Danish medical device company committed to the field of dermatology. Our CE marked 20 MHz HIFU systems deliver noninvasive ultrasound to target areas in the human skin, destroying target tissue, while surrounding tissue remains unharmed."
>
> — TOOsonix A/S

Clinical Device Manufacturers with Regulatory Approvals continued

Wuxi Haiying Electronic Medical Systems CO, LTD

Devices

1	1		
Total device	**Approved device**		

Name	Status	Treatment guidance	Planning guidance
HY2900	✚	US guidance	—

Approvals

1	1	1	1
Approved indication	**Region**	**Country**	**Total approval***

Indication	Region	Country	Agency and date
Women's health			
Uterine fibroids	Asia	China	NMPA, 2016

✚ Devices with regulatory approvals.

* The product of the number of approving agencies and the number of indications defined therein. More than one device may be approved for the same indication.

Approved Clinical Devices

Acoustic MedSystems

TheraVision

No image

Alpinion Medical Systems

Alpius 900

Uterine adenomyosis
Uterine fibroids

As ambassadors for the technology to the broader public audience, we often get asked what focused ultrasound medical devices look like. This is a photographic index of focused ultrasound devices that are commercially available. The photos included were provided by the manufacturers. If there is no image, we could not secure a photo of the device by the publication date.

Approved Clinical Devices continued

Changjiangyuan Technology Development

NUTAS - Non-invasive Ultrasound Tumor Ablation System	No image
SUPER Knife - Focused Beam Therapy System	No image

Approved Clinical Devices continued

Chongqing Haifu Medical Technology

CZB

Rhinitis

CZF

Cervicitis

No image

Approved Clinical Devices continued

Chongqing Haifu Medical Technology continued

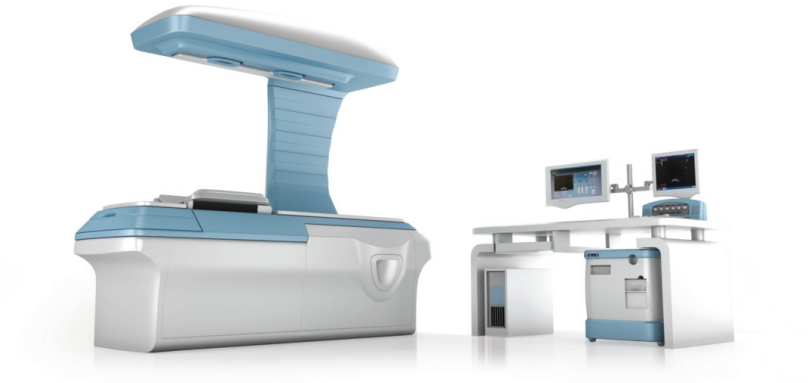
JC

Bone cancer
Breast tumors, benign
Breast tumors, malignant
Kidney tumors
Liver tumors
Pancreatic tumors, malignant
Soft tissue tumors, benign
Uterine adenomyosis
Uterine fibroids

JC200 series

Includes JC200, JC200A, JC200B, JC200C,JC200D, JC200D0, JC200D1, JC200D2, JC200D3, JC210, JC220

Bone cancer
Breast tumors, benign
Breast tumors, malignant
Kidney tumors
Liver tumors
Pancreatic tumors, malignant
Soft tissue tumors, benign
Uterine adenomyosis
Uterine fibroids



JC300 series

Includes JC300, JC300P, JC300S

Bone cancer
Breast tumors, benign
Breast tumors, malignant
Kidney tumors
Liver tumors
Pancreatic tumors, malignant
Soft tissue tumors, benign
Uterine adenomyosis
Uterine fibroids

Approved Clinical Devices continued

Chongqing Haifu Medical Technology continued

JCQ-B series
Includes JCQ-B100, JCQ-B130, JCQ-B150

Bone cancer
Breast tumors, benign
Breast tumors, malignant
Kidney tumors
Liver tumors
Pancreatic tumors, malignant
Uterine adenomyosis
Uterine fibroids

Approved Clinical Devices continued

EDAP TMS

Ablatherm

Benign prostatic hyperplasia
Prostate cancer

Focal One

Benign prostatic hyperplasia
Prostate cancer

Approved Clinical Devices continued

EpiSonica

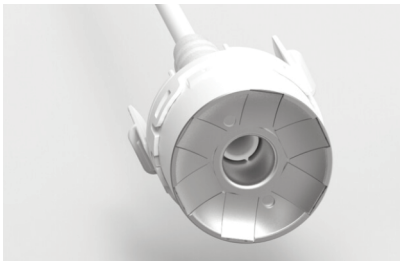
ArcBLATE (ARC-100M)

Soft tissue cancer

EyeTechCare

EyeOP1

Glaucoma

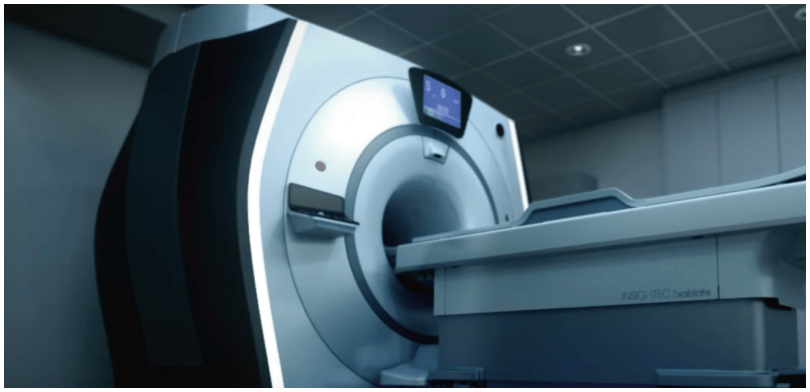


Approved Clinical Devices continued

Insightec

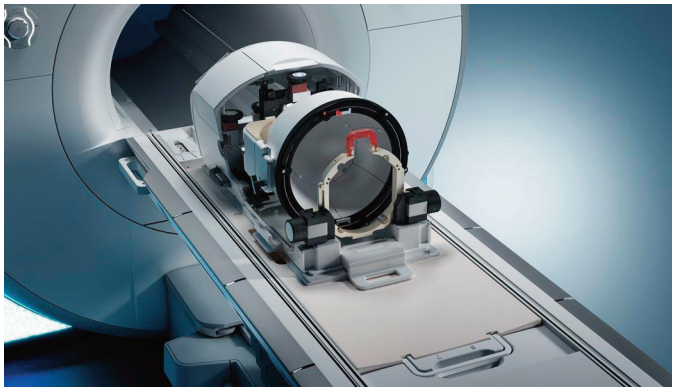
Exablate Body

Arthritis, facetogenic
Bone cancer
Bone metastases
Bone tumors, benign
Multiple myeloma
Prostate cancer
Uterine adenomyosis
Uterine fibroids



Exablate Neuro

Depression
Essential tremor
Neuropathic pain
Obsessive-compulsive disorder
Parkinson's disease, dyskinesia
Parkinson's disease, tremor



Exablate Prostate

Benign prostatic hyperplasia
Prostate cancer

Approved Clinical Devices continued

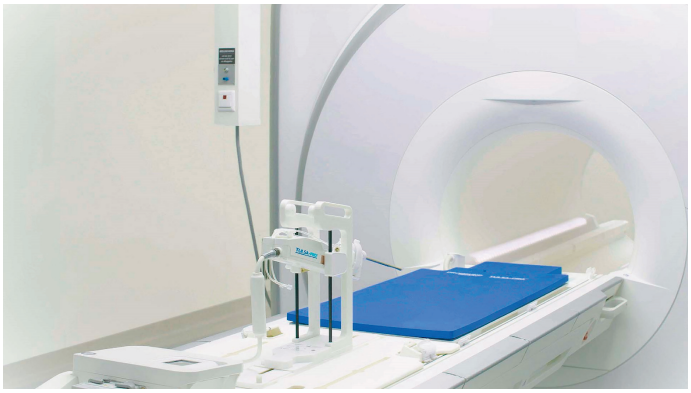
Profound Medical

Sonalleve

Bone metastases
Desmoid tumors
Osteoid osteoma
Uterine adenomyosis
Uterine fibroids

TULSA-PRO

Benign prostatic hyperplasia
Prostate cancer

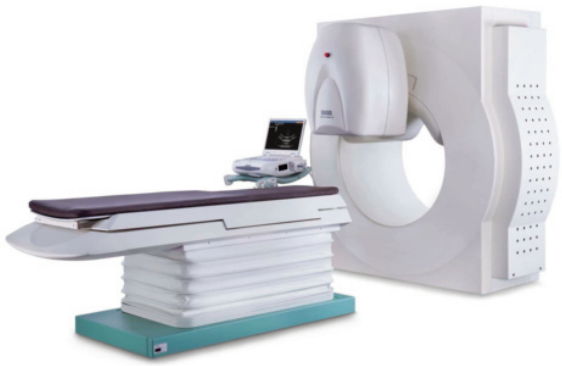


Approved Clinical Devices continued

Shanghai A&S Science Technology Development

HIFUNIT9000

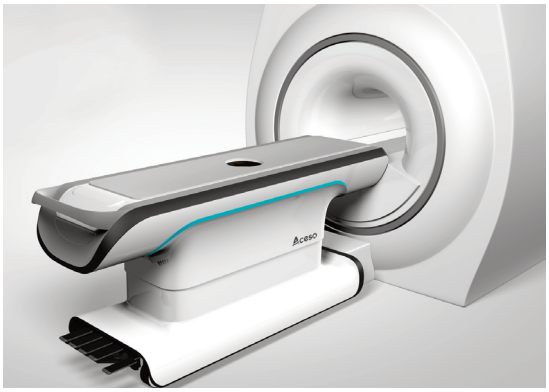
Bone metastases
Breast tumors, malignant
Liver tumors
Soft tissue cancer
Uterine fibroids



Shanghai Shende Green Medical Era Healthcare Technology

Aceso

Bone metastases



Approved Clinical Devices continued

Shenzhen PRO-HITU Medical Technology

PRO2008

Uterine adenomyosis
Uterine fibroids

PRO300

Uterine fibroids

PRO5G

Hyperplasia of the vulva
Lichen sclerosis

Approved Clinical Devices continued

Sonablate

Sonablate

Benign prostatic hyperplasia
Prostate cancer

Sonatherm

Benign prostatic hyperplasia
Prostate cancer

Approved Clinical Devices continued

Theraclion

Echopulse

Breast tumors, benign
Thyroid

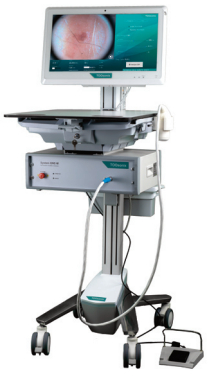
SONOVEIN

Varicose veins

Approved Clinical Devices continued

TOOsonix

System ONE-M



Wuxi Haiying Electronic Medical Systems

HY2900

Uterine fibroids

No image

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