

2023

Regulatory Approvals



FOCUSED
ULTRASOUND
FOUNDATION

Overview

Before a medical procedure can be considered for clinical use, the technology underlying that procedure—for instance, the focused ultrasound device—must first obtain regulatory approval from a governing body. Approval is based on clinical data demonstrating that the technology is safe and effective. Examples of regulatory approvals include the CE Mark for most countries in Europe and device approval from the US Food and Drug Administration (FDA).

Approvals are also disease-specific, meaning each device must go through the regulatory process for every different disease and/or condition it aims to treat.

Once a regulatory body clears a device for a select indication, physicians can begin treating patients on a commercial basis, but oftentimes on a cash-pay basis. For the treatment to be financially accessible by the greater patient population, it must obtain reimbursement.

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.

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Development Stage Advancements and New Indications

2022

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New global regulatory approvals

China NMPA	Macau ISAF	United Arab Emirates MOHAP
 <p>Benign prostatic hyperplasia</p>	 <p>Benign prostatic hyperplasia Prostate tumors</p>	 <p>Essential tremor Neuropathic pain Parkinson's disease, tremor</p>
Israel AMAR	Taiwan FDA	United Kingdom MHRA
 <p>Prostate tumors</p>	 <p>Parkinson's disease, tremor</p>	 <p>Benign prostatic hyperplasia Essential tremor Neuropathic pain Parkinson's disease, tremor Prostate Tumors</p>

FUS Regulatory Approvals by Indication and Region
Graphic



Global Landscape of Approved Indications and Manufacturers

Indication regional approvals	Indications	Manufacturers
	Cardiovascular	
● ●	Varicose veins	Theraclion
	Endocrine disorders	
● ●	Thyroid nodules	Theraclion
	Gastrointestinal	
●	Liver metastases	Chongqing Haifu Medical Technology
● ●	Liver tumors	Chongqing Haifu Medical Technology
●		Shanghai A&S
● ●	Pancreatic tumors	Chongqing Haifu Medical Technology
	Musculoskeletal	
● ● ● ●	Arthritis, facetogenic	Insightec
● ● ● ●	Bone cancer	Insightec
● ● ● ●	Bone metastases	Insightec
● ● ● ●		Profound Medical
●		Shanghai A&S
● ● ● ●	Bone tumors, benign	Insightec
●	Desmoid tumors	Profound Medical
● ● ● ●	Multiple myeloma	Insightec
● ●	Osteoid osteoma	Chongqing Haifu Medical Technology
● ●		Profound Medical
● ●	Soft tissue cancer	Chongqing Haifu Medical Technology
●		EpiSonica
●		Shanghai A&S
● ●	Soft tissue tumors, benign	Chongqing Haifu Medical Technology

Approval regions

- North America
- South America
- Europe
- Oceania
- Asia
- Africa

REGULATORY APPROVALS

Global Landscape of Approved Indications and Manufacturers continued

Indication regional approvals	Indications	Manufacturers
	Neurological	
●	Depression	Insightec
● ● ● ● ●	Essential tremor	Insightec
● ● ● ●	Neuropathic pain	Insightec
●	Obsessive-compulsive disorder	Insightec
● ● ●	Parkinson's disease, dyskinesia	Insightec
● ● ● ● ●	Parkinson's disease, tremor	Insightec
	Ophthalmological	
● ●	Glaucoma	EyeTechCare
	Pulmonary	
● ●	Rhinitis	Chongqing Haifu Medical Technology
	Urological	
●	Benign prostatic hyperplasia	EDAP TMS
●		Insightec
●		Profound Medical
● ● ● ● ●		Sonablate
● ● ● ● ●		Chongqing Haifu Medical Technology
● ● ● ● ●	Prostate cancer	EDAP TMS
● ● ● ● ●		Insightec
● ● ● ● ●		Profound Medical
● ● ● ● ● ●		Sonablate
	Women's health	
● ●	Breast tumors, benign	Theraclion
● ● ● ● ●	Breast tumors, malignant	Chongqing Haifu Medical Technology
● ● ● ● ●		Shanghai A&S
● ● ● ● ●		Theraclion
● ● ● ● ●	Cervicitis	Chongqing Haifu Medical Technology

Approval regions

- North America
- South America
- Europe
- Oceania
- Asia
- Africa

Global Landscape of Approved Indications and Manufacturers continued

Indication regional approvals	Indications	Manufacturers
	Women's health continued	
●	Hyperplasia of the vulva	Shenzhen PRO-HITU Medical
●	Lichen sclerosis	Shenzhen PRO-HITU Medical
●	Uterine adenomyosis	Alpinion Medical Systems
●		Chongqing Haifu Medical Technology
●		Insightec
●		Profound Medical
●		Shenzhen PRO-HITU Medical
●		Alpinion Medical Systems
●		Chongqing Haifu Medical Technology
●		Insightec
●		Profound Medical
●		Shanghai A&S
●	Shenzhen PRO-HITU Medical	
●	Uterine fibroids	Wuxi Haiying Electronic Medical

Approval regions

- North America
- South America
- Europe
- Oceania
- Asia
- Africa

REGULATORY APPROVALS

FUS Regulatory Approvals by Region and Manufacturer

	North America	Europe	Asia	South America	Oceania	Africa
Indications						
Cardiovascular						
Varicose veins		▲	▲			
Endocrine						
Thyroid nodules		▲	▲			
Gastrointestinal						
Liver metastases		●				
Liver tumors		●	● ●			
Pancreatic tumors		●	●			
Musculoskeletal						
Arthritis, facetogenic		●	●	●	●	
Bone cancer		●	●	●	●	
Bone metastases	●	■ ●	■ ● ●	■ ●	■ ●	
Bone tumors, benign		●	●	●	●	
Desmoid tumors		■				
Multiple myeloma		●	●	●	●	
Osteoid osteoma	■	■ ●	■ ●			
Soft tissue cancer		●	● ● ●			
Soft tissue tumors, benign		●	●			

Manufacturers

- North America**
- Profound Medical, *Canada*
 - Sonablate, *US*

- Europe**
- ▲ EDAP TMS, *France*
 - ▲ EyeTechCare, *France*
 - ▲ Theraclion, *France*

- Asia**
- Alpinion Medical Systems, *South Korea*
 - Chongqing Haifu Medical Technology, *China*
 - EpiSonica, *Taiwan*
 - Insightec, *Israel*
 - Shanghai A&S, *China*
 - Shenzhen PRO-HITU Medical, *China*
 - Wuxi Haiying Electronic Medical, *China*

FUS Regulatory Approvals by Region and Manufacturer continued

	North America	Europe	Asia	South America	Oceania	Africa
Indications						
Neurological						
Depression			●			
Essential tremor	●	●	●	●	●	
Neuropathic pain		●	●	●	●	
OCD			●			
Parkinson's dyskinesia	●	●	●			
Parkinson's tremor	●	●	●	●	●	
Ophthalmological						
Glaucoma		▲	▲			
Pulmonary						
Rhinitis		●	●			
Urological						
BPH	■ ■ ▲ ●	■	■	■	■	
Kidney tumors		●	●			
Prostate cancer	■ ■ ▲ ●	■ ■ ▲ ●	■ ■ ▲ ●	■ ▲ ●	■ ●	■
Women's health						
Breast tumors, benign		▲	▲			
Breast tumors, malignant		●	▲ ● ●			
Cervicitis			●			
Hyperplasia of the vulva			●			
Lichen sclerosis			●			
Uterine adenomyosis		■ ● ●	■ ● ● ●	■ ●	■ ●	
Uterine fibroids	■ ●	■ ● ● ● ● ●	■ ● ● ● ● ● ●	■ ●	■ ●	

Manufacturers

- North America**
- Profound Medical, Canada
 - Sonablate, US

- Europe**
- ▲ EDAP TMS, France
 - ▲ EyeTechCare, France
 - ▲ Theracision, France

- Asia**
- Alpinion Medical Systems, South Korea
 - Chongqing Haifu Medical Technology, China
 - EpiSonica, Taiwan
 - Insightec, Israel
 - Shanghai A&S, China
 - Shenzhen PRO-HITU Medical, China
 - Wuxi Haiying Electronic Medical, China

REGULATORY APPROVALS

North America

FUS Regulatory Approvals by Country and Manufacturer

Indications	Bahamas	Barbados	Canada	Costa Rica	Dominican Republic	US	
	Ministry of Health	Ministry of Health and Wellness	Health Canada, Medical Devices Bureau	Ministerio de Salud	MISPAS	FDA, Center for Devices & Radiological Health	
Musculoskeletal							
Bone metastases			●			●	
Osteoid osteoma						■	
Neurological							
Essential tremor			●			●	
Parkinson's dyskinesia						●	
Parkinson's tremor						●	
Urological							
BPH			■	■	■	■ ■ ▲ ●	
Prostate cancer	■	■	■ ■ ▲	■	■	■ ■ ▲ ●	
Women's health							
Uterine fibroids			■ ●			●	

Manufacturers

North America

- Profound Medical, *Canada*
- Sonablate, *US*

Europe

- ▲ EDAP TMS, *France*
- ▲ EyeTechCare, *France*
- ▲ Theraction, *France*

Asia

- Alpinion Medical Systems, *South Korea*
- Chongqing Haifu Medical Technology, *China*
- EpiSonica, *Taiwan*
- Insightec, *Israel*
- Shanghai A&S, *China*
- Shenzhen PRO-HITU Medical, *China*
- Wuxi Haiying Electronic Medical, *China*

Europe

FUS Regulatory Approvals by Country and Manufacturer

Indications	Belarus	Europe	Russia	Turkey	United Kingdom
	MOH	CE Marking	Rosdravnadzor	TITUBB	MHRA
Cardiovascular					
Varicose veins		▲			
Endocrine					
Thyroid nodules		▲	▲		
Gastrointestinal					
Liver metastases		●			
Liver tumors		●	●		
Pancreatic tumors		●	●		
Musculoskeletal					
Arthritis, facetogenic		●	●	●	
Bone cancer		●	●	●	
Bone metastases	●	■ ●	●	●	
Bone tumors, benign		●	●	●	
Desmoid tumors		■			
Multiple myeloma		●	●	●	
Osteoid osteoma		■ ●	●		
Soft tissue cancer		●	●		
Soft tissue tumors, benign		●	●		

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REGULATORY APPROVALS

Europe

FUS Regulatory Approvals by Country and Manufacturer continued

	Belarus	Europe	Russia	Turkey	United Kingdom	
Indications	MOH	CE Marking	Roszdraznadzor	TITUBB	MHRA	
Neurological						
Essential tremor		●	●	●	●	
Neuropathic pain		●	●	●	●	
Parkinson's dyskinesia			●			
Parkinson's tremor		●	●	●	●	
Ophthalmological						
Glaucoma		▲				
Pulmonary						
Rhinitis		●				
Urological						
BPH		■	■		■	
Kidney tumors		●	●			
Prostate cancer	●	■ ■ ▲ ●	■ ▲ ●	●	■	
Women's health						
Breast tumors, benign		▲	▲			
Breast tumors, malignant		●	●			
Uterine adenomyosis		■ ● ●	●	●		
Uterine fibroids	●	■ ● ● ● ● ●	● ●	●		

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 - Shenzhen PRO-HITU Medical, China
 - Wuxi Haiying Electronic Medical, China

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REGULATORY APPROVALS

Asia

FUS Regulatory Approvals by Country and Manufacturer

Indications	China	Hong Kong	India	Israel	Japan	Kazakhstan	Kuwait	Macau	Malaysia
	NMPA	MDD	CDSCO	AMAR	MHLW	NCEM	MOH FDCD	ISAF	MDA
Cardiovascular									
Varicose veins		▲							
Endocrine									
Thyroid nodules		▲							▲
Gastrointestinal									
Liver tumors	● ●								
Pancreatic tumors	●								
Musculoskeletal									
Arthritis, facetogenic		●				●			
Bone cancer		●		●		●			
Bone metastases	●	●				●	●		■
Bone tumors, benign		●				●			
Multiple myeloma		●				●			
Osteoid osteoma	●								
Soft tissue cancer	● ●								
Soft tissue tumors, benign	●								
Neurological									
Depression									
Essential tremor	●	●	●	●	●	●			
Neuropathic pain		●	●	●		●			
OCD									
Parkinson's dyskinesia					●				
Parkinson's tremor	●	●	●	●	●	●			

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Asia

FUS Regulatory Approvals by Country and Manufacturer continued

Indications	Pakistan	Philippines	Saudi Arabia	Singapore	South Korea	Taiwan	Thailand	UAE	Vietnam
	DRAP	FDA	SFDA	HSA	MFDS	FDA	FDA	MOHAP	DMEW
Cardiovascular									
Varicose veins				▲					
Endocrine									
Thyroid nodules				▲	▲	▲	▲		
Gastrointestinal									
Liver tumors					●				
Pancreatic tumors					●				
Musculoskeletal									
Arthritis, facetogenic					●		●		
Bone cancer							●		
Bone metastases			●	■	●		●		■
Bone tumors, benign							●		
Multiple myeloma							●		
Osteoid osteoma				■					
Soft tissue cancer						●			
Soft tissue tumors, benign									
Neurological									
Depression					●				
Essential tremor		●		●	●	●	●	●	
Neuropathic pain		●			●		●	●	
OCD					●				
Parkinson's dyskinesia					●				
Parkinson's tremor		●		●	●	●	●	●	

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REGULATORY APPROVALS

Asia

FUS Regulatory Approvals by Country and Manufacturer

	China	Hong Kong	India	Israel	Japan	Kazakhstan	Kuwait	Macau	Malaysia
Indications	NMPA	MDD	CDSCO	AMAR	MHLW	NCEM	MOH FDCD	ISAF	MDA
Ophthalmological									
Glaucoma	▲								
Pulmonary									
Rhinitis	●								
Urological									
BPH	■	■	■	■	■			■	
Kidney tumors	●								
Prostate cancer	■	■ ●	■	■ ●		●		■	
Women's health									
Breast tumors, benign		▲							
Breast tumors, malignant	● ●								▲
Cervicitis	●								
Hyperplasia of the vulva	●								
Lichen sclerosis	●								
Uterine adenomyosis	●	●		●		●			■
Uterine fibroids	■ ● ● ● ● ● ●	●		●	●	●	●		■

Manufacturers

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 - ▲ Theracision, *France*

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 - Shanghai A&S, *China*
 - Shenzhen PRO-HITU Medical, *China*
 - Wuxi Haiying Electronic Medical, *China*

Asia

FUS Regulatory Approvals by Country and Manufacturer continued

	Pakistan	Philippines	Saudi Arabia	Singapore	South Korea	Taiwan	Thailand	UAE	Vietnam
Indications	DRAP	FDA	SFDA	HSA	MFDS	FDA	FDA	MOHAP	DMEW
Ophthalmological									
Glaucoma									
Pulmonary									
Rhinitis									
Urological									
BPH					■				■
Kidney tumors									
Prostate cancer	■			■	■ ▲	■	●		■
Women's health									
Breast tumors, benign				▲	▲	▲			
Breast tumors, malignant							▲		
Cervicitis									
Hyperplasia of the vulva									
Lichen sclerosus									
Uterine adenomyosis					● ●		●		■
Uterine fibroids			■ ●	■ ●	■ ● ● ● ● ●	● ●	● ●		■

Manufacturers

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 - ▲ EyeTechCare, France
 - ▲ Theracision, France

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 - Insightec, Israel
 - Shanghai A&S, China
 - Shenzhen PRO-HITU Medical, China
 - Wuxi Haiying Electronic Medical, China

REGULATORY APPROVALS

South America

FUS Regulatory Approvals by Country and Manufacturer

Indications	Argentina	Brazil	Chile	Colombia	Ecuador	Peru
	ANMAT	ANVISA	ANAMED	INVIMA	ANRCVS	DIGEMED
Musculoskeletal						
Arthritis, facetogenic			●			
Bone cancer			●			
Bone metastases	■		●			
Bone tumors, benign			●			
Multiple myeloma			●			
Neurological						
Essential tremor	●	●	●	●		●
Neuropathic pain	●	●	●	●		●
Parkinson's tremor	●	●	●	●		●
Urological						
BPH	■			■	■	
Prostate cancer	■	▲	●	■	■	
Women's health						
Uterine adenomyosis	■		●			
Uterine fibroids	■		●			

Manufacturers

- North America**
- Profound Medical, *Canada*
 - Sonablate, *US*

- Europe**
- ▲ EDAP TMS, *France*
 - ▲ EyeTechCare, *France*
 - ▲ Theraclion, *France*

- Asia**
- Alpinion Medical Systems, *South Korea*
 - Chongqing Haifu Medical Technology, *China*
 - EpiSonica, *Taiwan*
 - Insightec, *Israel*
 - Shanghai A&S, *China*
 - Shenzhen PRO-HITU Medical, *China*
 - Wuxi Haiying Electronic Medical, *China*

South America

FUS Regulatory Approvals by Country and Manufacturer continued

Indications	Trinidad and Tobago	
	Ministry of Health	
Musculoskeletal		
Arthritis, facetogenic		
Bone cancer		
Bone metastases		
Bone tumors, benign		
Multiple myeloma		
Neurological		
Essential tremor		
Neuropathic pain		
Parkinson's tremor		
Urological		
BPH	■	
Prostate cancer	■	
Women's health		
Uterine adenomyosis		
Uterine fibroids		

Manufacturers

- North America**
- Profound Medical, *Canada*
 - Sonablate, *US*

- Europe**
- ▲ EDAP TMS, *France*
 - ▲ EyeTechCare, *France*
 - ▲ Theraction, *France*

- Asia**
- Alpinion Medical Systems, *South Korea*
 - Chongqing Haifu Medical Technology, *China*
 - EpiSonica, *Taiwan*
 - Insightec, *Israel*
 - Shanghai A&S, *China*
 - Shenzhen PRO-HITU Medical, *China*
 - Wuxi Haiying Electronic Medical, *China*

REGULATORY APPROVALS

Oceania

FUS Regulatory Approvals by Country and Manufacturer

Indications	Australia	New Zealand
	TGA	MEDSAFE
Musculoskeletal		
Arthritis, facetogenic	●	●
Bone cancer	●	●
Bone metastases	■ ●	■ ●
Bone tumors, benign	●	●
Multiple myeloma	●	●
Neurological		
Essential tremor	●	
Neuropathic pain	●	
Parkinson's tremor	●	
Urological		
BPH	■	
Prostate cancer	■ ●	●
Women's health		
Uterine adenomyosis	■ ●	■ ●
Uterine fibroids	■ ●	■ ●

Manufacturers

- North America**
- Profound Medical, *Canada*
 - Sonablate, *US*

- Europe**
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 - ▲ EyeTechCare, *France*
 - ▲ Theracision, *France*

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 - EpiSonica, *Taiwan*
 - Insightec, *Israel*
 - Shanghai A&S, *China*
 - Shenzhen PRO-HITU Medical, *China*
 - Wuxi Haiying Electronic Medical, *China*

Africa

FUS Regulatory Approvals by Country and Manufacturer

Indications	South Africa	
	MCC	
Urological		
Prostate cancer	■	

Manufacturers

North America

- Profound Medical, *Canada*
- Sonablate, *US*

Europe

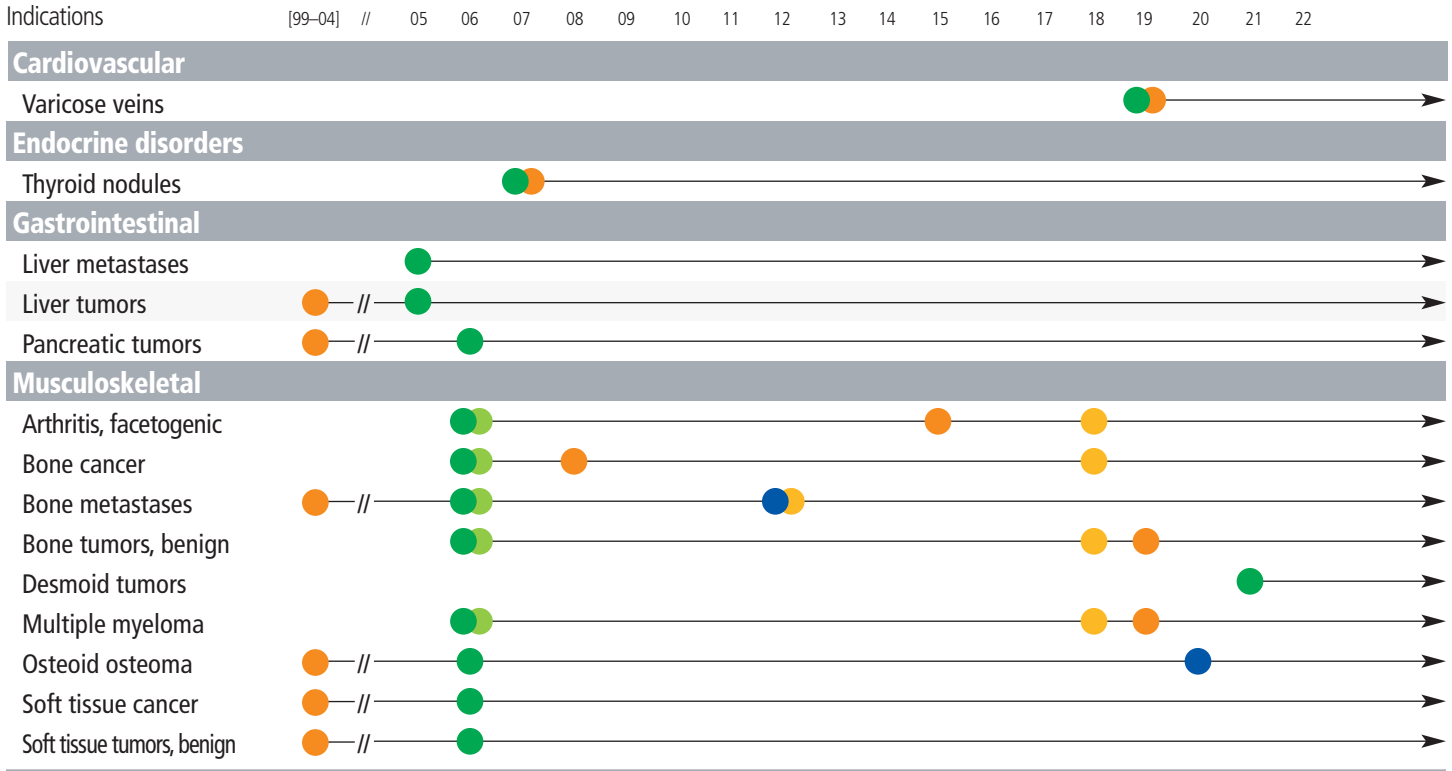
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- ▲ EyeTechCare, *France*
- ▲ Theraction, *France*

Asia

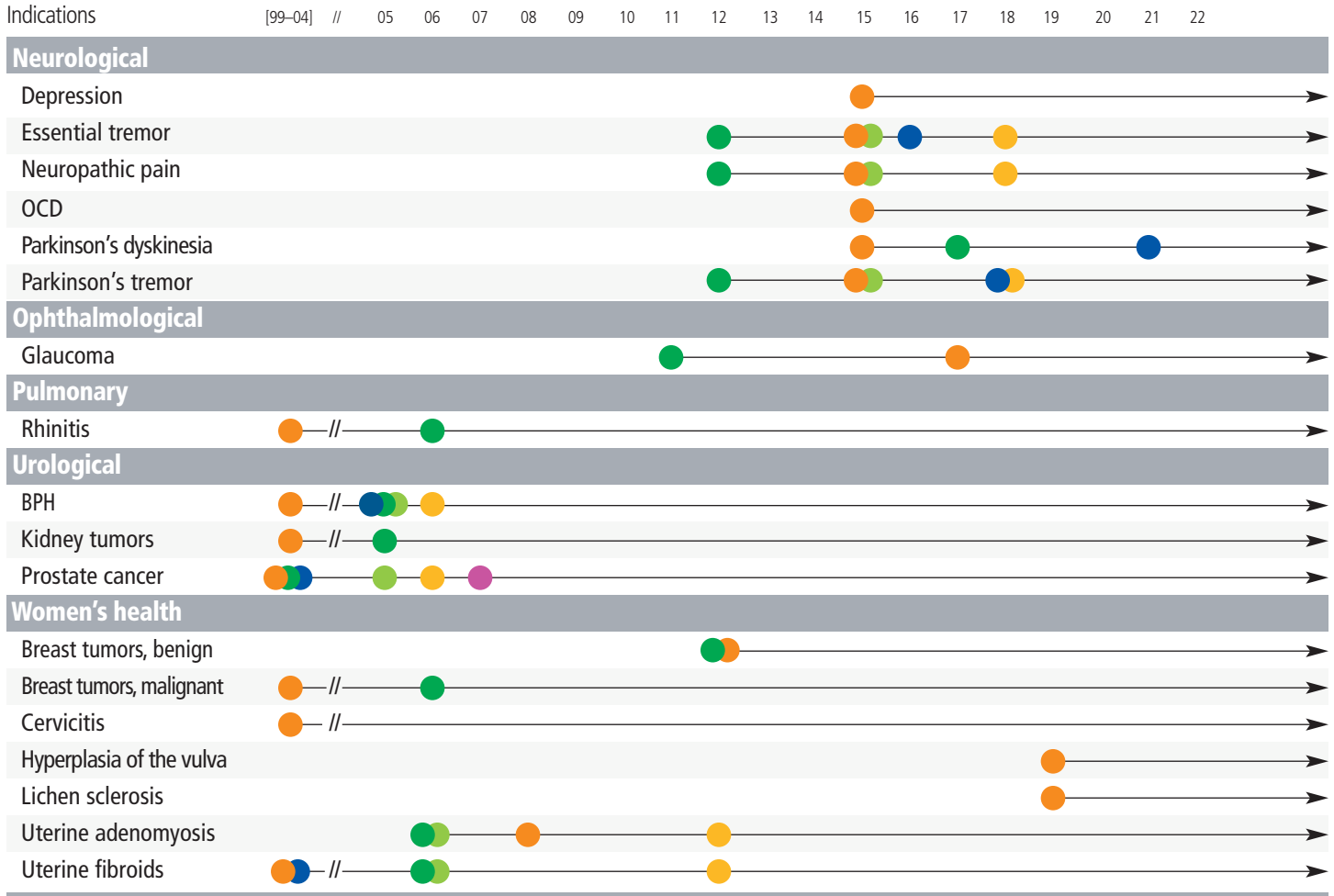
- Alpinion Medical Systems, *South Korea*
- Chongqing Haifu Medical Technology, *China*
- EpiSonica, *Taiwan*
- Insightec, *Israel*
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- Wuxi Haiying Electronic Medical, *China*

REGULATORY APPROVALS

FUS Regulatory Approvals by Indication and Region



FUS Regulatory Approvals by Indication and Region continued

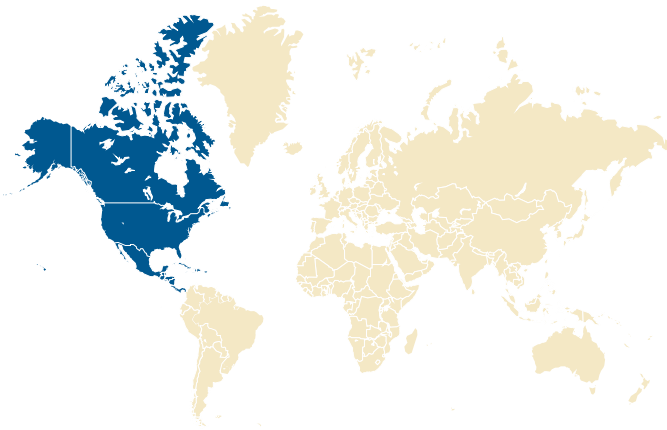


REGULATORY APPROVALS

North America

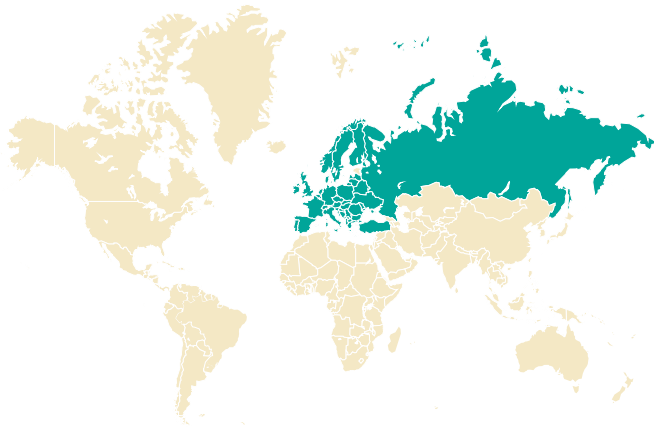
FUS Regulatory Approvals by Indication

8 Approvals



Europe
FUS Regulatory Approvals by Indication

27
Approvals



- Approval**
- Approval begin date
 - ▬ Approval end date
- Europe**
- Belarus, MOH
 - Europe, CE Marking
 - Russia, Roszdravnadzor
 - Turkey, TITUBB
 - United Kingdom, MHRA

REGULATORY APPROVALS

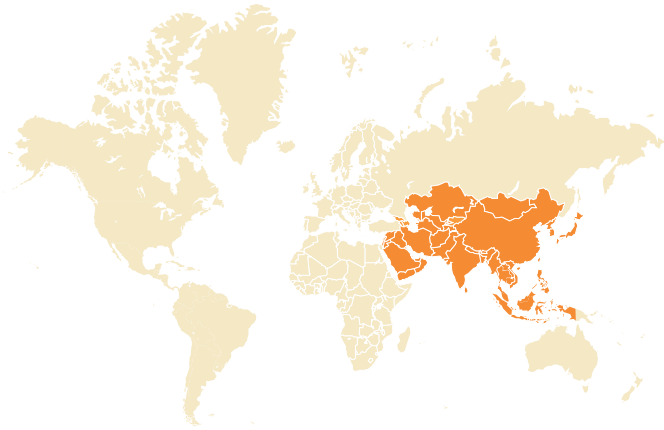
Europe

FUS Regulatory Approvals by Indication continued



Asia
FUS Regulatory Approvals by Indication

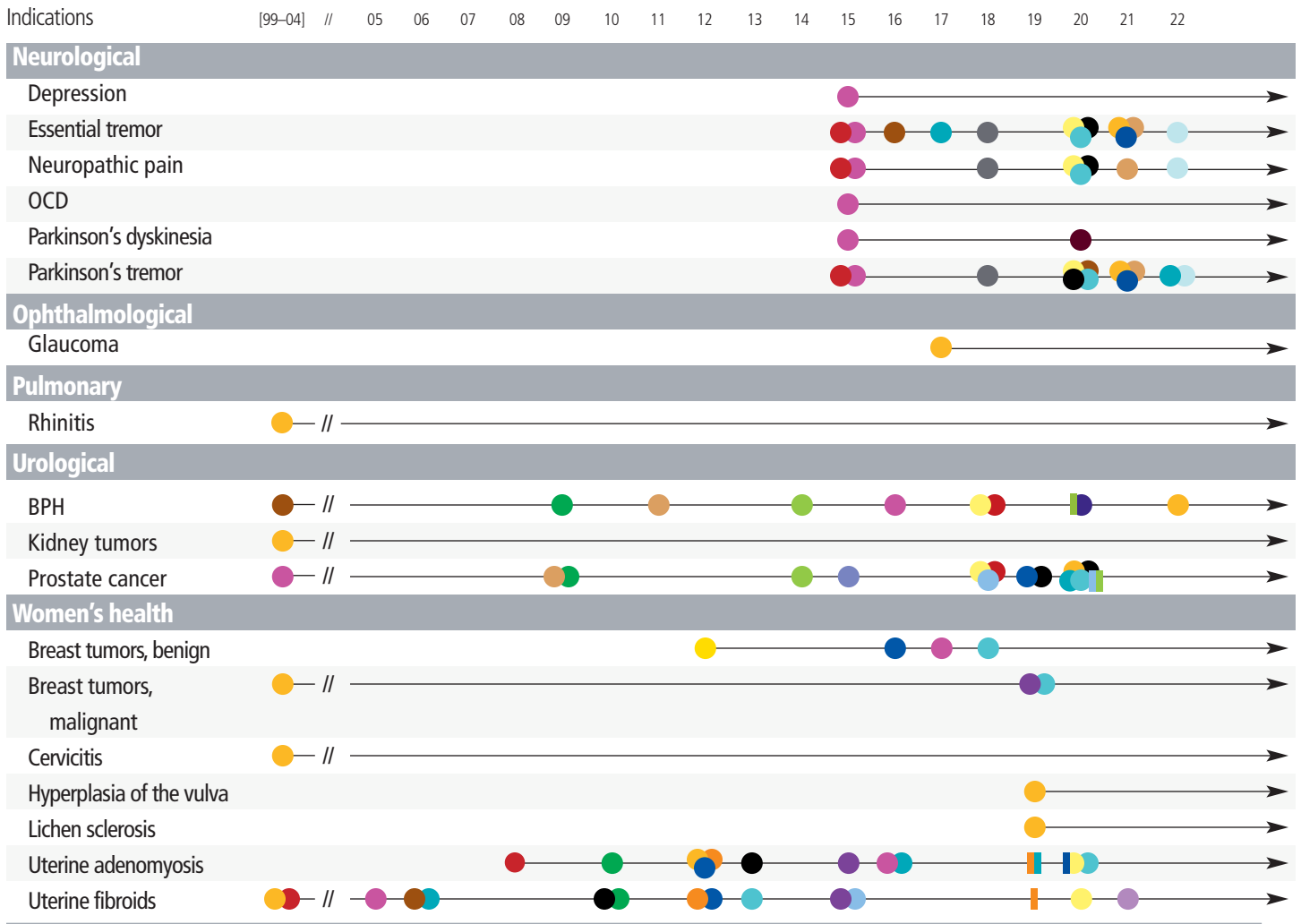
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Approvals



REGULATORY APPROVALS

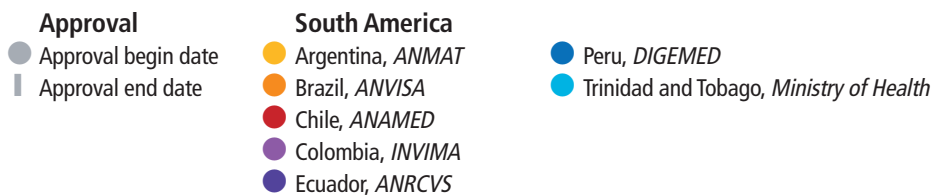
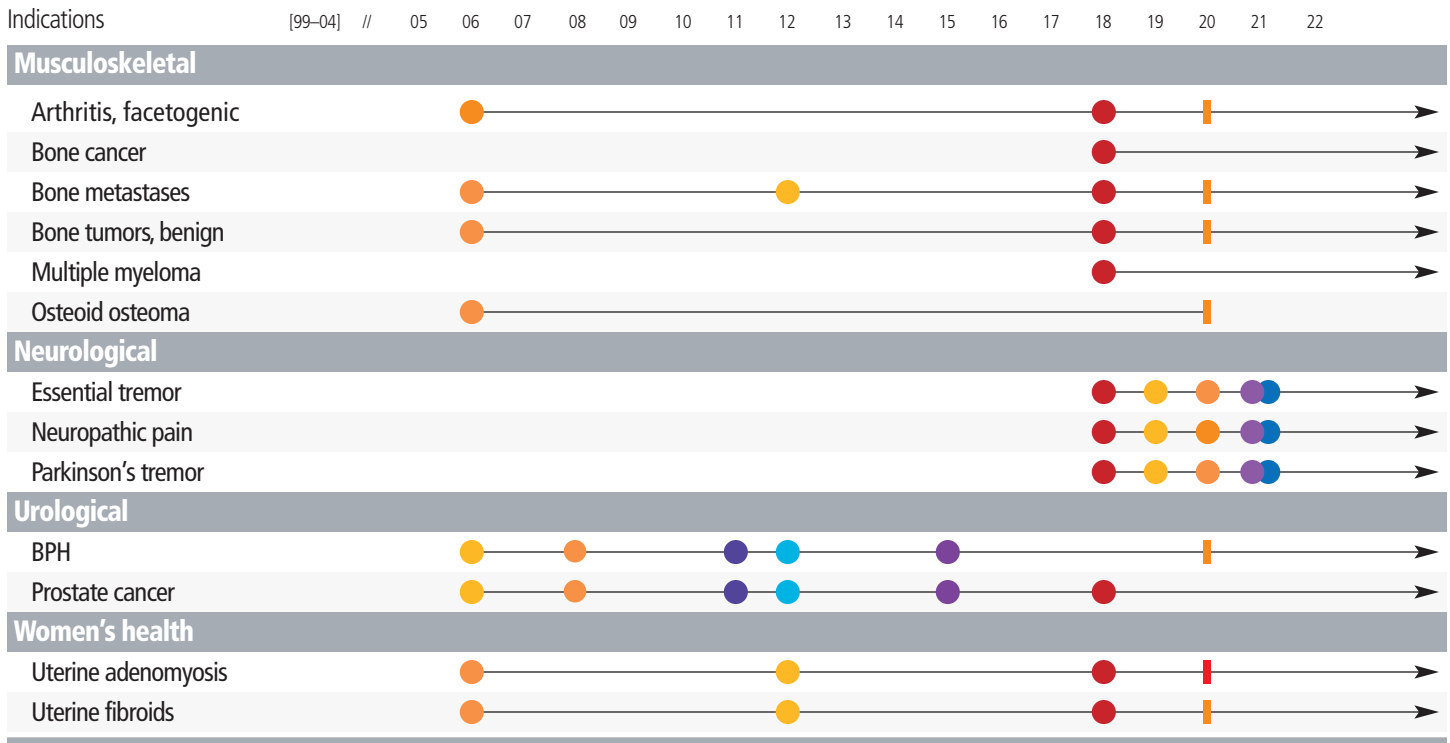
Asia

FUS Regulatory Approvals by Indication continued



South America
FUS Regulatory Approvals by Indication

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Approvals

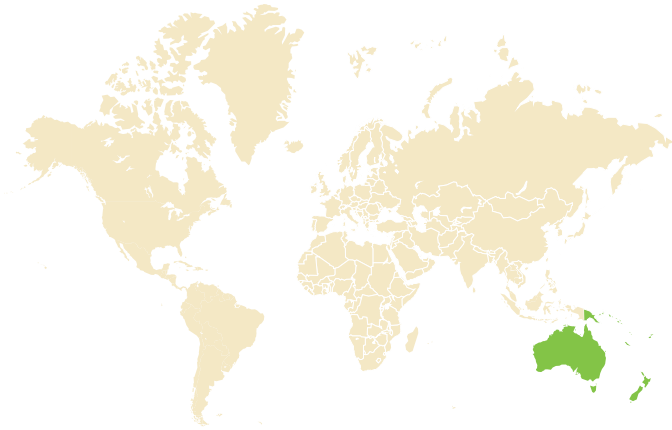


REGULATORY APPROVALS

Oceania

FUS Regulatory Approvals by Indication

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Approvals

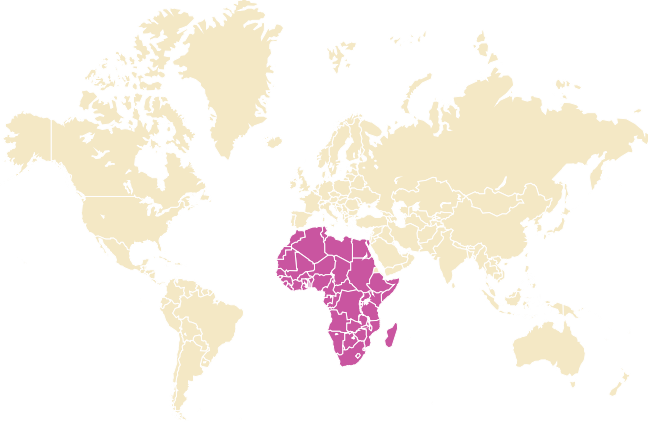


Approval
 ● Approval begin date
 | Approval end date

Oceania
 ● Australia, TGA
 ● New Zealand, MEDSAFE

Africa
FUS Regulatory Approvals by Indication

1
Approval



- Approval**
- Approval begin date
- ▮ Approval end date
- Africa**
- South Africa, MCC