

# Medical and Nonmedical Ultrasound

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# What Are the Products?

- Electronic products that emit acoustic radiation.
- EPRC regulations identify four categories of these products:
  - Ultrasonic therapy
  - Diagnostic ultrasound
  - Medical ultrasound other than therapy or diagnostic
  - Nonmedical ultrasound

# 21 CFR 1002.1

Manufacturer							Dealer & Distributor
Products	Product reports 1002.10	Supplemental reports 1002.11	Abbreviated reports 1002.12	Annual Reports 1002.13	Test records 1002.30(a)	Distribution records 1002.30(b)	Distribution records 1002.40 and 1002.41
<b>ACOUSTIC</b>							
<b>Ultrasound Therapy (1050.10)</b>	X	X		X	X	X	X
<b>Diagnostic Ultrasound</b>			X				
<b>Medical Ultrasound other than therapy or diagnostic</b>	X	X					
<b>Nonmedical ultrasound</b>			X				

# Ultrasonic Therapy Products



- There is only one performance standard for ultrasonic therapy products, 21 CFR 1050.10, which applies only to ultrasonic therapy products for use in physical therapy.
- Physical therapy products, also known as diathermy products, are intended to deliver gentle therapeutic heat to tissues.
- Ultrasonic diathermy devices are capable of heating deep tissue to a therapeutic temperature range of 40-45°C for treatment of pain, muscle spasms, and joint contractures.



# Diagnostic Ultrasound Products

- Diagnostic ultrasound uses high frequency sound waves for real-time visualization of structures inside the body.
- Wide range of uses:
  - Pulsed doppler and pulsed echo imaging systems
  - Fetal doppler monitor
  - Echocardiograph and cardiovascular blood flowmeter
  - Bone sonometer
- Diagnostic ultrasound products have a long history of safe use, dating back to the 1940s.



# Medical Ultrasound other than Therapy or Diagnostic Products

- High intensity ultrasound devices for therapies other than diathermy and physical therapy.
- Includes devices that use focused high intensity ultrasound energy to ablate tissue.
  - MR-guided focused ultrasound
  - High intensity ultrasound system for prostate tissue ablation
- Used for treatment of cancer, e.g., prostate tumors, and treatment of benign tumors, e.g., symptomatic uterine leiomyomas (fibroids).

# Nonmedical Ultrasound Products

- Nonmedical ultrasound includes a variety of products:
  - Pest repellants
  - Industrial cleaning systems
  - Ultrasonic distance sensors used in cars
- These products use high frequency sound waves.

# What Are Our Concerns?

## ***Medical ultrasound***

- Ultrasound energy has the potential to produce biological effects such as heating of tissue or creation of bubbles in body fluids or tissue (cavitation).
- Safety and effectiveness issues are considered during the medical device premarket review of diagnostic, therapeutic, and other medical ultrasound products.

## ***Nonmedical ultrasound***

- FDA has received only a few adverse event reports for these products.



# Current FDA Approaches

## *Medical ultrasound*

- The safety profile of medical ultrasound products is considered acceptable when they are operated for their intended uses by trained professionals who follow the manufacturer's labeling.
- Safety issues have been and will continue to be handled through medical device premarket regulatory processes as well as under other medical device regulatory authorities.

# 21 CFR 1002.1

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<b>ACOUSTIC</b>							
<b>Ultrasound Therapy (1050.10)</b>	X	X		X	X	X	X
<b>Diagnostic Ultrasound</b>			X				
<b>Medical Ultrasound other than therapy or diagnostic</b>	X	X					
<b>Nonmedical ultrasound</b>			X				

# Current FDA Approaches

## ***Medical ultrasound***

- Since February 24, 1986, under the authority of 21 CFR 1002.50(b), FDA has exempted all manufacturers and importers of diagnostic ultrasound products from EPRC initial and model change report requirements under 21 CFR 1002.10 and 1002.12 if they have submitted a premarket notification (510(k)) as required by the medical device regulations.

# Current FDA Approaches

## *Nonmedical ultrasound*

- There is minimal benefit to the receipt and review of abbreviated reports for these products, given the absence of performance standards for nonmedical ultrasound and the limited evidence of safety concerns.

# Proposed Approach

- FDA would like to update the reporting requirements under 21 CFR 1002.1 to no longer require product reports, supplemental reports, abbreviated reports, annual reports, test records, or distribution records for medical and nonmedical acoustic products.
- FDA believes the current reporting requirements and performance standard are an unnecessary burden and a source of confusion for these products.
- This reporting is redundant for medical device premarket submissions.
- There is no performance standard to consider when reports of nonmedical products are reviewed.



# Proposed Approach

- FDA believes that the performance standard in 21 CFR 1050.10 is outdated compared with more recent guidance documents and standards.
- For all medical ultrasonic products, FDA proposes continuing reliance on the premarket medical device review of safety and effectiveness, using guidance documents and recognized consensus standards.
- The premarket medical device review process permits an in-depth review of the safety and effectiveness of the design, labeling, and performance.

# Proposed Approach



- A disadvantage to eliminating EPRC reporting is the inability to track nonmedical ultrasound products, but we do not have evidence to support continued tracking.
- All ultrasound device manufacturers would still be required to submit certain reports under:
  - 21 CFR 1002.20 (Reporting of Accidental Radiation Occurrences)
  - 21 CFR 1003 (Notification of Defects or Failure to Comply),
  - 21 CFR 1004 (Repurchase, Repair, or Replacement of Electronic Products).

# Questions for TEPRSSC

- What is the committee's opinion of the strategy of relying on medical device premarket reviews to address safety concerns with medical ultrasound devices and no longer requiring the EPRC product report monitoring specified in 21 CFR 1002.1 and the performance standard?



# Questions for TEPRSSC

- Is the committee aware of any nonmedical ultrasound device safety concerns that warrant continuing the EPRC requirement for abbreviated product reports for nonmedical ultrasound?

