How FDA Regulates MRI Systems

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Promote and protect the health of the public by ensuring the **safety** and **effectiveness** of medical devices and the safety of radiation-emitting electronic products





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How is MRI regulated by FDA?

FDA regulates manufacturers of the equipment and the equipment itself

- LAWS (legally binding requirements)
 - FD&C Act of 1938 ("The Act")
 - Medical Device Amendments of 1976
- REGULATIONS (legally binding requirements)
- GUIDANCES (recommendations; typically not legally binding)



FDA's regulation of magnetic resonance imaging equipment includes:

- Premarket requirements

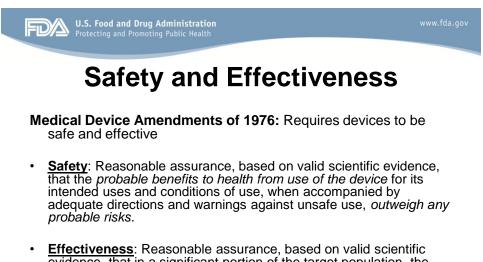
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- Postmarket requirements
- Requirements for investigational studies

Other State and Federal Agencies

Regulate use of magnetic resonance imaging devices through recommendations and requirements for:

- personnel qualifications
- institutional quality assurance programs
- facility accreditation



 <u>Effectiveness</u>: Reasonable assurance, based on valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended use and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

Device Class and Pre-Market Requirements

Device Class	Controls	FDA Pre-market review process
Class I	General Controls	Most exempt
Class II	General Controls +	510(k)
	Special Controls	clearance
Class III	General Controls +	PMA
	Pre-Market Approval	approval

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510(k) Premarket Notifications: How Is Substantial Equivalence Determined?

Submission from the manufacturer

- compares new device to predicate device(s)
- demonstrates that the new device is as safe and effective as predicate ٠ Predicate = legally U.S. marketed device

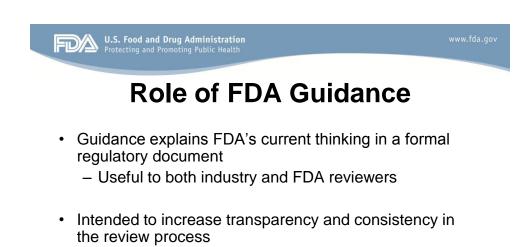
Substantially equivalent (SE)

- same intended use AND same technological characteristics OR
- same intended use AND different technological characteristics (e.g., change in material, design, energy source, software) AND these differences do not raise different questions of safety and effectiveness

When do manufacturers need to submit a 510(k)?

- Introducing the device into commercial distribution for the first time
- Making a significant change to a currently marketed device
 - (i) that could significantly affect the safety or effectiveness of the device (e.g. a significant change or modification in design, material, chemical composition, energy source, or manufacturing process)
 - (ii) A major change or modification in the intended use of the device.

21 CFR 807.81



- Most guidance documents do not establish legally enforceable responsibilities
 - Manufacturers can develop alternate methods of demonstrating substantial equivalence

Role of FDA Guidance

- FDA guidance document specific to MRI premarket ٠ submissions
 - "Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices (1998)"
 - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidan ce/GuidanceDocuments/ucm073817.htm



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Role of Standards

- Voluntary FDA-recognized standards
 - Can simplify 510(k) submissions
 - CDRH Standards Program and liaisons
- CDRH recognized consensus standards relevant to MRI
 - IEC 60601-2-33
 - NEMA MS series
 - ASTM F2503, F2052, F2119, F2182, F2213

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FDA's Post-market surveillance system: MedWatch

- FDA's nationwide adverse event reporting system, MedWatch, serves to monitor medical device performance after a device is approved or cleared for marketing.
- Manufacturers, Consumers and User Facilities (such as hospitals) report under MedWatch.
 - Alternative hospital-based reporting mechanism MedSun
 - Children's is a MedSun Hospital
 - MedSun representatives are Jeff Hooper and Linda Matthews
- Database which stores reported events known as MAUDE. Publically available: <u>http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm</u>

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Postmarket Requirements Who has to report what and when?

Medical Device Manufacturers <u>must</u> report:

- Deaths
- Serious injuries
- Malfunctions to FDA

User Facilities <u>must</u> report:

- Deaths to FDA and to the manufacturer
- Serious injuries to the manufacturer
- Alternative mechanism for User Facilities is MedSun

Voluntary Reporting at 1-800-FDA-1088

Reported problems occurring in MRI environment

- Adverse Event Reports received
 January 1, 2006 December 31, 2011.
- · Broad search to capture all problems in the MR environment
 - devices present in the MRI suite;
 - devices that accompany a patient;
 - items that are not medical device but may pose risk (jewelry, mops, etc.)
- · Keyword search for "MR" or "MRI,"
 - excluded "Mr." "Mrs" or "MRSA"



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Reported problems occurring in MRI environment

- Thermal-related issues
- Compatibility issues
- Projectile events
- Hearing issues
- Nerve stimulation/shocking

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Thermal-Related Issues

Reported patient outcomes :

- Burns (second and third degree)
- Blisters
- Redness
- Heating or warmth

Most reported incidents attributed to:

- no padding or inadequate padding
- improper positioning
- accessory device on or with patient (e.g. electrodes, pulse oximeters, thermal blankets, t-shirt with silver threads)
- implanted device (e.g. rod, metal clip implant)

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Compatibility Issues

Reported patient outcomes

non-functional device after a scan was completed (e.g. infusion pump stalls)

Most reported incidents attributed to:

- Missing labelling
- MR Unsafe labelling, yet a scan was performed.
- Misunderstood labelling

Projectile Events

Reported patient outcomes:

- Death
- Crush injury or other blunt trauma

Most reported incidents are attributed to:

- _ site access issues
- product mislabeling as MR Safe/MR Conditional;
- labeling was not available;
- screening oversights



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Hearing Issues

Reported patient outcomes:

ringing in ears _

:

hearing loss (transient + permanent)

Most reported incidents attributed to:

- No hearing protection _
- Faulty hearing protection

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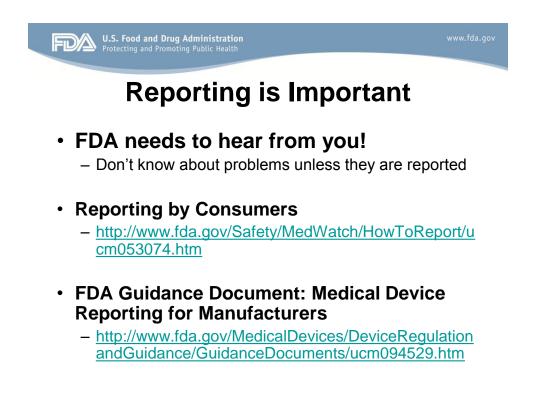
Nerve Stimulation/Shocking Events

Reported patient outcomes

- Peripheral nerve stimulation
- Shocking

Most reported incidents attributed to:

associated with accessory or implanted devices



Significant Risk/Non-significant Risk **MRI Studies**

- In general, FDA considers MRI studies to be nonsignificant risk provided the MRI equipment does not exceed specific operating conditions¹
- This includes the development of MRI coils, pulse ٠ sequences, and post processing algorithms
 - Such activity would be supervised by the local IRB



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Significant Risk Operating Conditions for MR systems

Static magnetic field

- >8T for adults, children and infants >1month
- >4T for infants <1month
- Specific Absorption Rate (SAR) above

Site	Dose	Time (min) equal to or greater than:	SAR (W/kg)
whole body	averaged over	15	4
head	averaged over	10	3
head or torso	per gram of tissue	5	8
extremities	per gram of tissue	5	12

¹ FDA guidance document, "Criteria for Significant Risk Investigations of Magnetic Resonance Devices," 2003 ttp://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM0 72688.pdf)

Significant Risk Operating Conditions for MR systems

Gradient Field Rate of Change

 Any time rate of change of gradient fields (dB/dt) sufficient to produce severe discomfort or painful nerve stimulation

Sound Pressure Level

- Peak unweighted sound pressure level >140dB
- A-weighted rms sound pressure level >99dBA with hearing protection in place



 Possible to have a SR study that involves an NSR MRI system (e.g. surgical procedure performed in 1.5T magnet or research software used to make patient care decisions)

Questions?

If you have questions about the level of risk in your study protocol:

- Submit a Risk-Determination request². ٠
- · Contact the Division of Radiological Health Janine Morris, Division Director (301) 796 - 5706 Janine.Morris@fda.hhs.gov

²http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/Investigational DeviceExemptionIDE/ucm046164.htm#pre_ide



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Thank you!

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