Contains Nonbinding Recommendations

Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices

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Guidance for Industry and Food and Drug Administration Staff

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This document supersedes "Guidance for Industry and FDA Staff - Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices" issued on July 14, 2003.

On June 20, 2014 this document was edited to amend a table on specific absorption rate (SAR) and make minor formatting and contact updates.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Magnetic Resonance and Electronic Products Branch
Division of Radiological Health
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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

This guidance describes the device operation conditions for magnetic resonance diagnostic devices that FDA considers significant risk for the purposes of determining whether a clinical study requires Agency approval of an Investigation Device Exemption (IDE). Magnetic resonance diagnostic devices are class II devices described under 21 CFR 892.1000. The product codes for these devices are:

LNH Magnetic Resonance Imaging System
LNI Magnetic Resonance Spectroscopic System

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Studies of Magnetic Resonance Diagnostic Devices

If a clinical study is needed to demonstrate substantial equivalence, i.e., conducted prior to obtaining 510(k) clearance of the device, the study must be conducted under the IDE regulation (21 CFR Part 812). FDA believes that a magnetic resonance diagnostic device used under any one of the operating conditions listed below is a significant risk device as defined in 21 CFR 812.3(m)(4) and, therefore, that studies involving such a device do not qualify for the abbreviated IDE requirements of 21 CFR 812.2(b). In addition to the requirement of having an FDA-approved IDE, sponsors of significant risk studies must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50).

Significant Risk Magnetic Resonance Diagnostic Devices

You should consider the following operating conditions when assessing whether a study may be considered significant risk:

- main static magnetic field
- specific absorption rate (SAR)
- gradient fields rate of change
- sound pressure level

Generally, FDA deems magnetic resonance diagnostic devices significant risk when used under any of the operating conditions described below.

Main Static Magnetic Field

Population	**Main static magnetic field greater than** (tesla)
adults, children, and infants aged > 1 month	8
neonates i.e., infants aged 1 month or less	4

Specific Absorption Rate (SAR)

Site	Dose	Time (min) equal to or greater than:	SAR (W/kg)
whole body	averaged over	15	>4
head	averaged over	10	>3.2

If you have questions about significant risk criteria related to local SAR, you may wish to contact FDA.

Gradient Fields 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 greater than 140 dB.

A-weighted root mean square (rms) sound pressure level greater than 99 dBA with hearing protection in place.

These criteria apply only to device operating conditions. Other aspects of the study may involve significant risks and the study, therefore, may require IDE approval regardless of operating conditions. See Blue Book Memorandum entitled **Significant Risk and Non-significant Risk Medical Device Studies (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126418.pdf)** for further discussion.

After FDA determines that the device is substantially equivalent, clinical studies conducted in accordance with the indications reviewed in the 510(k), including clinical design validation studies conducted in accordance with the quality systems regulation, are exempt from the investigational device exemptions (IDE) requirements. However, such studies must be performed in conformance with 21 CFR 56 and 21 CFR 50.