## **CFR** Code of Federal Regulations Title 21



FDA Home Medical Devices Databases 5



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## **New Search**

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2012]
[CITE: 21CFR892.1000]



TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 892 -- RADIOLOGY DEVICES

Subpart B--Diagnostic Devices

Sec. 892.1000 Magnetic resonance diagnostic device.

(a) Identification. A magnetic resonance diagnostic device is intended for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images and/or spectra may also be produced. The device includes hydrogen-1 (proton) imaging, sodium-23 imaging, hydrogen-1 spectroscopy, phosphorus-31 spectroscopy, and chemical shift imaging (preserving simultaneous frequency and spatial information).

(b) Classification. Class II.

[53 FR 5078, Feb. 1, 1989]