§ 892.1420 Radionuclide test pattern phantom.

(a) Identification. A radionuclide test pattern phantom is a device that consists of an arrangement of radiopaque or radioactive material sealed in a solid pattern intended to serve as a test for a performance characteristic of a nuclear medicine imaging device.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §892.9.


§ 892.1540 Nonfetal ultrasonic monitor.

(a) Identification. A nonfetal ultrasonic monitor is a device that projects a continuous high-frequency sound wave into body tissue other than a fetus to determine frequency changes (doppler shift) in the reflected wave and is intended for use in the investigation of nonfetal blood flow and other nonfetal body tissues in motion. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) Classification. Class II.


§ 892.1550 Ultrasonic pulsed doppler imaging system.

(a) Identification. An ultrasonic pulsed doppler imaging system is a device that combines the features of continuous wave doppler-effect technology with pulsed-echo effect technology and is intended to determine stationary body tissue characteristics, such as depth or location of tissue interfaces or dynamic tissue characteristics such as velocity of blood or tissue motion. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) Classification. Class II.