TABLE 4—Continued

21 CFR	Device
880.5120	Manual adjustable hospital bed.
880.5180	Burn sheet.
880.6250	Patient examination glove.
880.6280	Medical insole.
880.6350	Battery-powered medical examination light.
880.6970	Liquid crystal vein locator.
884.5150	Nonpowered breast pump.
884.5425	Scented or scented deodorized menstrual pad.
884.5435	Unscented menstrual pad.
886.4370	Keratome (AC powered).
888.5960	Cast removal instrument (AC powered).
892.1300	Nuclear rectilinear scanner.
892.1320	Nuclear uptake probe.
892.1330	Nuclear whole body scanner.
892.1410	Nuclear electrocardiograph synchronizer.
892.1610	Diagnostic x-ray beam limiting device.
892.1620	Cine or spot flourographic x-ray camera.
892.1760	Diagnostic x-ray tube housing assembly.
892.1770	Diagnostic x-ray tube mount.
892.1830	Radiographic patient cradle.
892.1850	Radiographic film cassette.
892.1860	Radiographic film/cassette changer.
892.1880	Wall-mounted radiographic cassette holder.
892.1890	Radiographic film illuminator.
892.1910	Radiographic grid.
892.1970	Radiographic ECG/respirator synchronizer.
892.1980	Radiologic table.
892.5770	Powered radiation therapy patient support assembly.
892.5780	Light beam patient position indicator.
892.5930	Therapeutic x-ray tube housing assembly.
892.6500	Personnel protective shield.

FDA has concluded that 18 of the 56 devices listed in Table 4 are not candidates for exemption from the requirement of premarket notification because they are currently classified into class II and/or class III. These devices are listed in Table 5.

TABLE 5

21 CFR	Device
872.3310	Coating material for resin fillings.
872.3820	Root canal filling resin.
872.5470	Orthodontic plastic bracket.
872.5500	Extraoral orthodontic headgear.
872.6770	Cartridge syringe.
884.5425	Scented or scented deodorized menstrual pad.
892.1610	Diagnostic x-ray beam limiting device.
892.1620	Cine or spot flourographic x-ray camera.
892.1760	Diagnostic x-ray tube housing assembly.
892.1770	Diagnostic x-ray tube mount.
892.1830	Radiographic patient cradle.
892.1850	Radiographic film cassette.
892.1860	Radiographic film/cassette changer.
892.1880	Wall-mounted radiographic cassette holder.
892.1980	Radiologic table.
892.5770	Powered radiation therapy patient support assembly.
892.5780	Light beam patient position indicator.
892.5930	Therapeutic x-ray housing assembly.

In accordance with section 513(e)(1) of the act (21 U.S.C. 360c(e)(1)), any interested person may petition FDA to reclassify a device based on new information respecting such a device and to exempt such a device from the requirement of premarket notification. The form and content required for such a petition are set forth in 21 CFR 860.123. The request and reasons supporting the request for exemption from the requirement of premarket notification should be included in the supplemental data sheet. If a device is reclassified into class I, FDA may also exempt the device from the requirement of premarket notification.

Thirteen of the 56 devices listed in Table 4 have already been exempted from premarket notification procedures on the dates listed below. These devices are listed in Table 6.

TABLE 6

Date	Federal Register citation	21 CFR	Device
Nov. 9, 1982	47 FR 50823	866.2600	Wood's fluorescent lamp.
June 12, 1989	54 FR 25042	868.1930	Stethoscope head.
Aug. 12, 1987	52 FR 30082	872.3730	Pantograph.
Apr. 5, 1989	54 FR 13828	872.6050	Saliva absorber.
Dec. 7, 1994	59 FR 63005	874.5220	Ear, nose, and throat drug administration device.
Aug. 25, 1987	52 FR 32110	874.5800	External nasal splint.
June 12, 1989	54 FR 25042	876.4890	Urological table and accessories (manually powered).
June 12, 1989	54 FR 25042	880.5110	Hydraulic adjustable hospital bed.
June 12, 1989	54 FR 25042	880.5120	Manual adjustable hospital bed.
Dec. 7, 1994	59 FR 63005	880.5180	Burn sheet.
June 12, 1989	54 FR 25042	880.6280	Medical insole.
Oct. 21, 1980	45 FR 69682	880.6350	Battery-powered medical examination light.
June 12, 1989	54 FR 25042	880.6970	Liquid crystal vein locator.

Ten of the 56 devices listed in Table 4 are candidates for exemption from the requirement of premarket notification. These devices, which are listed in Table 7, along with the flotation cushion (§ 890.3175) and the traction accessory (§ 890.5925), are being proposed for premarket notification exemption elsewhere in today's issue of the **Federal Register**.

TABLE 7

21 CFR	Device
862.2230	Chromatographic separation material for clinical use.
872.2230	Dental floss (including devices made of inert materials).
874.1060	Acoustic chamber for audiometric testing.
874.4140	Ear, nose, and throat bur.
874.4175	Nasopharyngeal catheter.