accessories for both the implanted and nonimplanted blood access device. The devices subject to this paragraph (b)(4) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

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PART 878—GENERAL AND PLASTIC SURGERY DEVICES

85. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 522, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371).

86. Section 878.4450 is amended by revising paragraph (b) to read as follows:

§ 878.4450 Nonabsorbable gauze for internal use.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

87. Section 878.4810 is amended by revising paragraph (b) to read as follows:

§ 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.

* * * * *

(b) *Classification*. (1) Class II.

(2) Class I for special laser gas mixtures used as a lasing medium for this class of lasers. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

88. Section 878.5350 is amended by revising paragraph (b) to read as follows:

§ 878.5350 Needle-type epilator.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

89. Section 878.5910 is amended by revising paragraph (b) to read as follows:

§ 878.5910 Pneumatic tourniquet.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

90. The authority citation for 21 CFR 880 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

91. Section 880.2720 is amended by revising paragraph (b) to read as follows:

§ 880.2720 Patient scale.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

92. Section 880.2900 is amended by revising paragraph (b) to read as follows:

§ 880.2900 Clinical color change thermometer.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

93. Section 880.5560 is amended by revising paragraph (b) to read as follows:

§ 880.5560 Temperature regulated water mattress.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

94. Section 880.6320 is amended by revising paragraph (b) to read as follows:

§ 880.6320 AC-powered medical examination light.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 882—NEUROLOGICAL DEVICES

95. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

96. Section 882.1410 is amended by revising paragraph (b) to read as follows:

§ 882.1410 Electroencephalograph electrode/lead tester.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

97. Section 882.4325 is amended by revising paragraph (b) to read as follows:

§ 882.4325 Cranial drill handpiece (brace).

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

98. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

99. Section 884.1550 is revised to read as follows:

§ 884.1550 Amniotic fluid sampler (amniocentesis tray.

(a) *Identification*. The amniotic fluid sampler (amniocentesis tray) is a collection of devices used to aspirate amniotic fluid from the amniotic sac via a transabdominal approach. Components of the amniocenteses tray include a disposable 3 inch 20 gauge needle with stylet and a 30 cc. syringe, as well as the various sample collection accessories, such as vials, specimen containers, medium, drapes, etc. The device is used at 16–18 weeks gestation for antepartum diagnosis of certain congenital abnormalities or anytime after 24 weeks gestation when used to assess fetal maturity.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

100. Section 884.1640 is amended by revising paragraph (b) to read as follows:

§ 884.1640 Culdoscope and accessories.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for culdoscope accessories that are not part of a specialized instrument or device delivery system; do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such culdoscope accessory instruments include: Lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (noninflatable) scissors, and suction/irrigation probe. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

101. Section 884.1690 is amended by revising paragraph (b) to read as follows:

§ 884.1690 Hysteroscope and accessories.

* * * * *

(b) Classification. (1) Class II (performance standards).

(2) Class I for hysteroscope accessories that are not part of a specialized instrument or device