

prescription lens, teaching attachment, inflation bulb, measuring device for panendoscope, photographic equipment for physiologic function monitor, special lens instrument for endoscope, smoke removal tube, rechargeable battery box, pocket battery box, bite block for endoscope, and cleaning brush for endoscope. The proposed exemption for the urine flow or volume measuring system (§ 876.1800 (21 CFR 876.1800)) is limited and would apply only to the disposable, nonelectrical urine flow rate measuring device and the nonelectrical urinometer. The proposed exemption for the electrically powered urological table and accessories (§ 876.4890 (21 CFR 876.4890)) is limited and would apply only to stirrups. The proposed exemption for the suprapubic urological catheter and accessories (§ 876.5090 (21 CFR 876.5090)) is limited and would apply only to the catheter punch instrument, nondisposable cannula and trocar, and gastro-urological trocar. The proposed exemption for the urological catheters and accessories (§ 876.5130 (21 CFR 876.5130)) is limited and would apply only to the ureteral stylet (guidewire), stylet for gastro-urological catheter, ureteral catheter holder, ureteral catheter adapter, and ureteral catheter connector. The proposed exemption for the urethral dilator (§ 876.5520 (21 CFR 876.5520)) is limited and would apply only to the urethrometer, urological bougie, filiform and filiform follower, and metal or plastic urethral sound. Finally, the proposed exemption for the blood access device and accessories (§ 876.5540 (21 CFR 876.5540)) is limited and would apply only to the following accessories for both the implanted and the nonimplanted blood access device: Cannula clamp, disconnect forceps, crimp plier, tub plier, crimp ring, and joint ring.

TABLE 9.—GENERAL AND PLASTIC SURGERY DEVICES

CFR section	Device
878.4450	Nonabsorbable gauze for internal use.
878.4810	Laser surgical instrument for use in general and plastic surgery and in dermatology.
878.5350	Needle-type epilator.
878.5910	Pneumatic tourniquet.

FDA is proposing to grant an exemption from the requirement of premarket notification for the devices listed in Table 9 above. The proposed exemption for the laser surgical instrument for use in general and plastic

surgery and in dermatology (§ 878.4810 (21 CFR 878.4810)) is limited and would apply only to gas mixtures used as the lasing medium for this class of lasers.

TABLE 10.—GENERAL HOSPITAL AND PERSONAL USE DEVICES

CFR section	Device
880.2720	Patient scale.
880.2900	Clinical color change thermometer.
880.6320	AC-powered medical examination light.
880.5560	Temperature regulated water mattress.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 10 above.

TABLE 11.—NEUROLOGICAL DEVICES

CFR section	Device
882.1410	Electroencephalograph electrode/lead tester.
882.4325	Cranial drill handpiece (brace).

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 11 above.

TABLE 12.—OBSTETRICAL AND GYNECOLOGICAL DEVICES

CFR section	Device
884.1550	Amniotic fluid sampler (amniocentesis tray).
884.1640	Culdoscope and accessories.
884.1690	Hysteroscope and accessories.
884.1700	Hysteroscopic insufflator.
884.1720	Gynecologic laparoscope and accessories.
884.1730	Laparoscopic insufflator.
884.4530	Obstetric-gynecological specialized manual instrument.
884.5150	Nonpowered breast pump.
884.5425	Scented or scented deodorized menstrual pad.
884.5435	Unscented menstrual pad.
884.5900	Therapeutic vaginal douche apparatus.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 12 above. The proposed exemption for the culdoscope and accessories (§ 884.1640 (21 CFR 884.1640)) and the laparoscope and accessories (§ 884.1720 (21 CFR

884.1720)) are limited and would apply only to culdoscope and laparoscope accessories, respectively, that are not part of a specialized instrument or device delivery system and which do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such culdoscope and laparoscope accessory instruments are limited to: 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 proposed exemption for the gynecological hysteroscope and accessories (§ 884.1690 (21 CFR 884.1690)) is limited and would apply only to the following manual accessories: Lens cleaning brush; cannula (without trocar or valves); clamp/hemostat/grasper; curette; instrument guide; forceps; dissector; mechanical (noninflatable); and scissors. The proposed exemption for the hysteroscopic or laparoscopic insufflator accessories (§§ 884.1700 and 884.1730 (21 CFR 884.1700 and 884.1730), respectively) is limited and would apply only to tubing and tubing/filter kits used for hysteroscopic or laparoscopic insufflation as single use tubing kits used for only one clinical purpose, i.e., pneumoperitoneum or intrauterine insufflation, but not both. The proposed exemption does not apply to accessories such as hysteroscopic introducer sheaths or Verres needles. The proposed exemption for the obstetric-gynecological specialized manual instruments (§ 884.4530 (21 CFR 884.4530)) is limited and would apply only to the following devices: Amniotome; uterine curette; cervical dilator (fixed-size bougies); cerclage needle; intrauterine device remover; uterine sound; and gynecological biopsy forceps. The proposed exemption for the nonpowered breast pump (§ 884.5150) is limited and would apply only if the device is using either a bulb or telescoping mechanism which does not develop more than 250 mm Hg suction, and the device materials that contact breast or breast milk do not produce cytotoxicity, irritation, or sensitization effects. The proposed exemption for the scented or scented deodorized menstrual pad (§ 884.5425 (21 CFR 884.5425)) and the unscented menstrual pad (§ 884.5435) is limited and would