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

69. Section 874.4140 is amended by revising paragraph (b) to read as follows:

§ 874.4140 Ear, nose, and throat bur.

* * * * *

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

70. Section 874.4175 is amended by revising paragraph (b) to read as follows:

§ 874.4175 Nasopharyngeal catheter.

* * * * *

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

71. Section 874.4350 is amended by revising paragraph (b) to read as follows:

§ 874.4350 Ear, nose, and throat fiberoptic light source and carrier.

* * * * *

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

72. Section 874.4770 is amended by revising paragraph (b) to read as follows:

§ 874.4770 Otoscope.

* * * * *

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

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

73. The authority citation for 21 CFR part 876 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).

74. Section 876.1075 is amended by revising paragraph (b) to read as follows:

§ 876.1075 Gastroenterology-urology biopsy instrument.

* * * * *

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

(2) Class I for the biopsy forceps cover and the nonelectric biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

75. Section 876.1400 is amended by revising paragraph (b) to read as follows:

§ 876.1400 Stomach pH electrode.

* * * * *

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

76. Section 876.1500 is amended by revising paragraph (b) to read as follows:

§ 876.1500 Endoscope and accessories.

* * * * *

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

(2) Class I for the photographic accessories for endoscope, miscellaneous bulb adapter for endoscope, binocular attachment for endoscope, eyepiece attachment for 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 devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

77. Section 876.1800 is amended by revising paragraph (b) to read as follows:

§ 876.1800 Urine flow or volume measuring system.

* * * * *

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

(2) Class I for the disposable, nonelectrical urine flow rate measuring device, and nonelectrical urinometer. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

78. Section 876.4590 is amended by revising paragraph (b) to read as follows:

§ 876.4590 Interlocking urethral sound.

* * * * *

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

79. Section 876.4890 is amended by revising paragraph (b) to read as follows:

§ 876.4890 Urological table and accessories.

* * * * *

(b) *Classification*. (1) Class II (performance standards) for the electrically powered urological table and accessories.

(2) Class I for the manually powered table and accessories, and for stirrups for electrically powered table. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

80. Section 876.5090 is amended by revising paragraph (b) to read as follows:

§ 876.5090 Suprapubic urological catheter and accessories.

* * * * *

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

(2) Class I for the catheter punch instrument, nondisposable cannula and trocar, and gastro-urological trocar. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

81. Section 876.5130 is amended by revising paragraph (b) to read as follows:

§ 876.5130 Urological catheter and accessories.

* * * * *

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

(2) Class I for the ureteral stylet (guidewire), stylet for gastro-urological catheter, ureteral catheter adapter, ureteral catheter connector, and ureteral catheter holder. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

82. Section 876.5450 is amended by revising paragraph (b) to read as follows:

§ 876.5450 Rectal dilator.

* * * * *

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

83. Section 876.5520 is amended by revising paragraph (b) to read as follows:

§ 876.5520 Urethral dilator.

* * * * *

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

(2) Class I for the urethrometer, urological bougie, filiform and filiform follower, and metal or plastic urethral sound. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

84. Section 876.5540 is amended by revising paragraph (b)(3) and by adding new paragraph (b)(4) to read as follows:

§ 876.5540 Blood access device and accessories.

* * * * *

(b) * * *

(3) Class II (performance standards) for accessories for both the implanted and the nonimplanted blood access devices not listed in paragraph (b)(4) of this section.

(4) Class I for the cannula clamp, disconnect forceps, crimp plier, tube plier, crimp ring, and joint ring,