TABLE 2.—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

CFR section	Device
862.2230	Chromatographic separation material for clinical use.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of device listed in Table 2 above.

TABLE 3.—IMMUNOLOGY AND MICROBIOLOGY DEVICES

CFR section	Device
866.2160	Coagulase plasma.
866.3720	Streptococcus spp. exoenzyme reagents.
866.5520	Immunoglobulin G (Fab fragment specific) immunological test system.
886.5530	Immunoglobulin G (Fc fragment specific) immunological test system.
866.5860	Total spinal fluid immunological test system.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 3 above.

TABLE 4.—ANESTHESIOLOGY DEVICES

CFR section	Device
868.1100	Arterial blood sampling kit.
868.1575	Gas collection vessel.
868.1870	Gas volume calibrator.
868.2300	Bourdon gauge flowmeter.
868.2320	Uncompensated thorpe tube flowmeter.
868.2340	Compensated thorpe tube flowmeter.
868.2350	Gas calibration flowmeter.
868.2610	Gas pressure gauge.
868.2620	Gas pressure calibrator.
868.2700	Pressure regulator.
868.2875	Differential pressure transducer.
868.2885	Gas flow transducer.
868.2900	Gas pressure transducer.
868.5100	Nasopharyngeal airway.
868.5110	Oropharyngeal airway.
868.5240	Anesthesia breathing circuit.
868.5300	Carbon dioxide absorbent.
868.5310	Carbon dioxide absorber.
868.5320	Reservoir bag.
868.5375	Heat and moisture condenser (artificial nose).
868.5460	Therapeutic humidifier for home use.
868.5530	Flexible laryngoscope.
868.5540	Rigid laryngoscope.
868.5550	Anesthetic gas mask.

TABLE 4.—ANESTHESIOLOGY DEVICES—Continued

CFR section	Device
868.5570	Nonrebreathing mask.
868.5580	Oxygen mask.
868.5590	Scavenging mask.
868.5600	Venturi mask.
868.5770	Tracheal tube fixation device.
868.5780	Tube introduction forceps.
868.5790	Tracheal tube stylet.
868.5810	Airway connector.
868.5820	Dental protector.
868.5860	Pressure tubing and accessories.
868.5975	Ventilator tubing.
868.5995	Tee drain (water trap).
868.6400	Calibration gas.
868.6820	Patient position support.
868.6885	Medical gas yoke assembly.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 4 above.

TABLE 5.—CARDIOVASCULAR DEVICES

CFR section	Device
870.2390	Phonocardiograph.
870.2600	Signal isolation system.
870.2620	Line isolation monitor.
870.2640	Portable leakage current alarm.
870.2810	Paper chart recorder.
870.3650	Pacemaker polymeric mesh bag.
870.3670	Pacemaker charger.
870.3690	Pacemaker test magnet.
870.3935	Prosthetic heart valve holder.
870.3945	Prosthetic heart valve sizer.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 5 above.

TABLE 6.—DENTAL DEVICES

CFR section	Device
872.1840	Dental x-ray position indicating device.
872.1850	Lead-lined position indicator.
872.4630	Dental operating light.
872.6390	Dental floss.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices in Table 6 listed above. The proposed exemption for dental floss (§ 872.6390 (21 CFR 872.6390)) is limited and would apply only when the device is composed of inert material and is not coated or impregnated with chemicals intended to provide a therapeutic benefit or interact with tissues of the oral cavity.

TABLE 7.—EAR, NOSE, AND THROAT DEVICES

CFR section	Device
874.1060	Acoustic chamber for audiometric testing.
874.1080	Audiometer calibration set.
874.4140	Ear, nose, and throat bur.
874.4175	Nasopharyngeal catheter.
874.4350	Ear, nose, and throat fiberoptic light source and carrier.
874.4770	Otoscope.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 7 above. The proposed exemption for the otoscope (§ 874.4770 (21 CFR 874.4770)) is limited and would apply only when used in the external ear canal.

TABLE 8.—GASTROENTEROLOGY-UROLOGY DEVICES

CFR section	Device
876.1075	Gastroenterology-urology biopsy instrument.
876.1400	Stomach pH electrode.
876.1500	Endoscope and accessories.
876.1800	Urine flow or volume measuring system.
876.4590	Interlocking urethral sound.
876.4890	Urological catheter and accessories.
876.5090	Suprapublic urological catheter and accessories.
876.5130	Urological catheter and accessories.
876.5450	Rectal dilator.
876.5520	Urethral dilator.
876.5540	Blood access device and accessories.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 8 above. The proposed exemption for the gastroenterology- urology biopsy instrument (§ 876.1075 (21 CFR 876.1075)) is limited and would apply only to the biopsy forceps cover and the nonelectric biopsy forceps. The proposed exemption for the endoscope and accessories (§ 876.1500 (21 CFR 876.1500)) is limited and would apply only to the following specified devices: Photographic accessories for endoscope, miscellaneous bulb adapter for endoscope, binocular attachment for endoscope, eyepiece attachment for