§ 868.6700

Anesthesia stool.

(a) Identification. An anesthesia stool is a device intended for use as a stool for the anesthesiologist in the operating room.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.


PART 870—CARDIOVASCULAR DEVICES

Subpart A—General Provisions

Sec.

870.1 Scope.

870.3 Effective dates of requirement for premarket approval.

870.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Cardiovascular Diagnostic Devices

870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm).

870.1100 Blood pressure alarm.

870.1110 Blood pressure computer.

870.1120 Blood pressure cuff.

870.1130 Noninvasive blood pressure measurement system.

870.1140 Venous blood pressure manometer.

870.1200 Diagnostic intravascular catheter.

870.1210 Continuous flush catheter.

870.1220 Electrode recording catheter or electrode recording probe.

870.1230 Fiberoptic oximeter catheter.

870.1240 Flow-directed catheter.

870.1250 Percutaneous catheter.

870.1270 Intracavitary phonocatheter system.

870.1280 Steerable catheter.

870.1290 Steerable catheter control system.

870.1300 Catheter cannula.

870.1310 Vessel dilator for percutaneous catheterization.

870.1330 Catheter guide wire.

870.1340 Catheter introducer.

870.1350 Catheter balloon repair kit.

870.1360 Syringe actuator for an injector.

870.1370 Catheter tip occluder.

870.1380 Catheter stylet.

870.1390 Trocar.

870.1425 Programmable diagnostic computer.

870.1435 Single-function, preprogrammed diagnostic computer.

870.1450 Densitometer.

870.1650 Angiographic injector and syringe.

870.1660 Indicator injector.

870.1670 Syringe actuator for an injector.

870.1750 External programmable pacemaker pulse generator.

870.1800 Withdrawal-infusion pump.

870.1875 Stethoscope.