§ 870.1350 Catheter balloon repair kit.
(a) Identification. A catheter balloon repair kit is a device used to repair or replace the balloon of a balloon catheter. The kit contains the materials, such as glue and balloons, necessary to effect the repair or replacement.
(b) Classification. Class III (premarket approval).
(c) Date PMA or notice of completion of a PDP is required. A PMA or notice of

§ 870.1290 Steerable catheter control system.
(a) Identification. A steerable catheter control system is a device that is connected to the proximal end of a steerable guide wire that controls the motion of the steerable catheter.
(b) Classification. Class II (performance standards).

§ 870.1300 Catheter cannula.
(a) Identification. A catheter cannula is a hollow tube which is inserted into a vessel or cavity; this device provides a rigid or semirigid structure which can be connected to a tube or connector.
(b) Classification. Class II (performance standards).

§ 870.1310 Vessel dilator for percutaneous catheterization.
(a) Identification. A vessel dilator for percutaneous catheterization is a device which is placed over the guide wire to enlarge the opening in the vessel, and which is then removed before sliding the catheter over the guide wire.
(b) Classification. Class II (performance standards).

§ 870.1320 Catheter guide wire.
(a) Identification. A catheter guide wire is a coiled wire that is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel.
(b) Classification. Class II (performance standards).

§ 870.1330 Catheter introducer.
(a) Identification. A catheter introducer is a sheath used to facilitate placing a catheter through the skin into a vein or artery.
(b) Classification. Class II (performance standards).

§ 870.1340 Catheter introducer.
(a) Identification. A catheter introducer is a sheath used to facilitate placing a catheter through the skin into a vein or artery.
(b) Classification. Class II (performance standards).

§ 870.1350 Catheter balloon repair kit.
(a) Identification. A catheter balloon repair kit is a device used to repair or replace the balloon of a balloon catheter. The kit contains the materials, such as glue and balloons, necessary to effect the repair or replacement.
(b) Classification. Class III (premarket approval).
(c) Date PMA or notice of completion of a PDP is required. A PMA or notice of