hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion. A PTCA catheter may also be intended for the treatment of acute myocardial infarction; treatment of in-stent restenosis (ISR) and/or post-deployment stent expansion.

(2) Classification. Class II (special controls). The special control for this device is “Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters.” See §870.1(e) for the availability of this guidance document.

(b) Cutting/scoring PTCA Catheter—(1) Identification. A cutting/scoring PTCA catheter is a balloon-tipped catheter with cutting/scoring elements attached, which is used in those circumstances where a high pressure balloon resistant lesion is encountered. A cutting/scoring PTCA catheter is intended for the treatment of hemodynamically significant coronary artery stenosis for the purpose of improving myocardial perfusion. A cutting/scoring PTCA catheter may also be indicated for use in complex type C lesions or for the treatment of in-stent restenosis.

(2) Classification. Class III (premarket approval). As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See §870.3.

§ 870.5225 External counter-pulsating device.

(1) Identification. An external counter-pulsating device is a noninvasive device used to assist the heart by applying positive or negative pressure to one or more of the body’s limbs in synchrony with the heart cycle.

(2) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of a PDP is required. No effective date has been established of the requirement for premarket approval. See §870.3.

§ 870.5300 DC-defibrillator (including paddles).

(a) Low-energy DC-defibrillator—(1) Identification. A low-energy DC-defibrillator is a device that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart or to terminate other cardiac arrhythmias. This generic type of device includes low energy defibrillators with a maximum electrical output of less than 360 joules of energy that are used in pediatric defibrillation or in cardiac surgery. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles.