AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

to the electrical or mechanical changes produced in the transducer.

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

§ 870.2855 Implantable Intra-aneurysm Pressure Measurement System.

(a) *Identification*. Implantable intra-aneurysm pressure measurement system is a device used to measure the intra-sac pressure in a vascular aneurysm. The device consists of a pressure transducer that is implanted into the aneurysm and a monitor that reads the pressure from the transducer.

(b) *Classification*. Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Implantable Intra-Aneurysm Pressure Measurement System.'' See § 870.1 (e) for the availability of this guidance document.

[71 FR 7871, Feb. 15, 2006]

§ 870.2860 Heart sound transducer.

(a) *Identification*. A heart sound transducer is an external transducer that exhibits a change in mechanical or electrical properties in relation to sounds produced by the heart. This device may be used in conjunction with a phonocardiograph to record heart sounds.

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

§ 870.2870 Catheter tip pressure transducer.

(a) *Identification*. A catheter tip pressure transducer is a device incorporated into the distal end of a catheter. When placed in the bloodstream, its mechanical or electrical properties change in relation to changes in blood pressure. These changes are transmitted to accessory equipment for processing.

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

§ 870.2880 Ultrasonic transducer.

(a) *Identification*. An ultrasonic transducer is a device applied to the skin to transmit and receive ultrasonic energy that is used in conjunction with an echocardiograph to provide imaging of cardiovascular structures. This device includes phased arrays and two-dimensional scanning transducers.

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

§ 870.2890 Vessel occlusion transducer.

(a) *Identification*. A vessel occlusion transducer is a device used to provide an electrical signal corresponding to sounds produced in a partially occluded vessel. This device includes motion, sound, and ultrasonic transducers.

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

§ 870.2900 Patient transducer and electrode cable (including connector).

(a) *Identification*. A patient transducer and electrode cable (including connector) is an electrical conductor used to transmit signals from, or power or excitation signals to, patient-connected electrodes or transducers.

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

§ 870.2910 Radiofrequency physiological signal transmitter and receiver.

(a) *Identification*. A radiofrequency physiological signal transmitter and receiver is a device used to condition a physiological signal so that it can be transmitted via radiofrequency from one location to another, e.g., a central monitoring station. The received signal is reconditioned by the device into its original format so that it can be displayed.

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

§ 870.2920 Telephone electrocardiograph transmitter and receiver.

(a) *Identification*. A telephone electrocardiograph transmitter and receiver is a device used to condition an electrocardiograph signal so that it can be transmitted via a telephone line to another location. This device also includes a receiver that reconditions the received signal into its original format so that it can be displayed. The device includes devices used to transmit and receive pacemaker signals.

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