§ 890.3710 Powered communication system.

(a) Identification. A powered communication system is an AC- or battery-powered device intended for medical purposes that is used to transmit or receive information. It is used by persons unable to use normal communication methods because of physical impairment. Examples of powered communication systems include the following: a specialized typewriter, a reading machine, and a video picture and word screen.

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §890.9.

§ 890.3725 Powered environmental control system.

(a) Identification. A powered environmental control system is an AC- or battery-powered device intended for medical purposes that is used by a patient to operate an environmental control function. Examples of environmental control functions include the following: to control room temperature, to answer a doorbell or telephone, or to sound an alarm for assistance.

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.