§ 880.6150 Ultrasonic cleaner for medical instruments.

(a) Identification. An ultrasonic cleaner for medical instruments is a device consisting of a stiff board used to increase the firmness of a bed.

(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 §880.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.