Food and Drug Administration, HHS

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, regarding general requirements concerning records and §820.198, regarding complaint files.

§890.5170 Powered flotation therapy bed.

(a) Identification. A powered flotation therapy bed is a device that is equipped with a mattress that contains a large volume of constantly moving water, air, mud, or sand. It is intended for medical purposes to treat or prevent a patient’s bedsores, to treat severe or extensive burns, or to aid circulation. The mattress may be electrically heated.

(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 §890.9.