§ 880.6265 Examination gown.

(a) Identification. An examination gown is a device intended for medical purposes that is made of cloth, paper, or other material that is draped over or worn by a patient as a body covering during a medical examination.

(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.

[72 FR 36362, July 3, 2007]

§ 880.6280 Medical insole.

(a) Identification. A medical insole is a device intended for medical purposes that is placed inside a shoe to relieve the symptoms of athlete’s foot infection by absorbing moisture.

(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.


§ 880.6300 Implantable radiofrequency transponder system for patient identification and health information.

(a) Identification. An implantable radiofrequency transponder system for patient identification and health information is a device intended to enable access to secure patient identification and corresponding health information. This system may include a passive implanted transponder, inserter, and scanner. The implanted transponder is used only to store a unique electronic identification code that is read by the scanner. The identification code is used to access patient identity and corresponding health information stored in a database.

(b) Classification. Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information.” See §880.1(e) for the availability of this guidance document. This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §880.9.

[69 FR 71704, Dec. 10, 2004]