§ 880.6260 \textit{Filtering facepiece respirator for use by the general public in public health medical emergencies.} 

(a) Identification. A filtering facepiece respirator for use by the general public in public health medical emergencies is a device that is a disposable half-facepiece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates placed over a cast to protect it from getting wet during a shower or a bath.

(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. If the device is not labeled or otherwise represented as sterile, it 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.


§ 880.6230 \textit{Tongue depressor.} 

(a) Identification. A tongue depressor is a device intended to displace the tongue to facilitate examination of the surrounding organs and tissues.

(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. If the device is not labeled or otherwise represented as sterile, it 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.


§ 880.6250 \textit{Patient examination glove.} 

(a) Identification. A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner’s hand or finger to prevent contamination between patient and examiner.

(b) Classification. Class I (general controls).

§ 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.


§ 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.

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