§ 880.6190 Mattress cover for medical purposes.

(a) Identification. A mattress cover for medical purposes is a device intended for medical purposes that is used to protect a mattress. It may be electrically conductive or contain a germicide.

(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 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 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).

§ 880.6260 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.