

§ 878.4100

room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses, commonly known as scrub suits, are excluded.

(b) *Classification.* (1) Class II (special controls) for surgical gowns and surgical masks. A surgical N95 respirator or N95 filtering facepiece respirator is not exempt if it is intended to prevent specific diseases or infections, or it is labeled or otherwise represented as filtering surgical smoke or plumes, filtering specific amounts of viruses or bacteria, reducing the amount of and/or killing viruses, bacteria, or fungi, or affecting allergenicity, or it contains coating technologies unrelated to filtration (e.g., to reduce and or kill microorganisms). Surgical N95 respirators and N95 filtering facepiece respirators are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9, and the following conditions for exemption:

(i) The user contacting components of the device must be demonstrated to be biocompatible.

(ii) Analysis and nonclinical testing must:

(A) Characterize flammability and be demonstrated to be appropriate for the intended environment of use; and

(B) Demonstrate the ability of the device to resist penetration by fluids, such as blood and body fluids, at a velocity consistent with the intended use of the device.

(iii) NIOSH approved under its regulation.

(2) Class I (general controls) for surgical apparel other than surgical gowns and surgical masks. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

[53 FR 23872, June 24, 1988, as amended at 65 FR 2317, Jan. 14, 2000; 83 FR 22848, May 17, 2018]

§ 878.4100 Organ bag.

(a) *Identification.* An organ bag is a device that is a flexible plastic bag intended to be used as a temporary receptacle for an organ during surgical procedures to prevent moisture loss.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in

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subpart E of part 807 of this chapter subject to § 878.9.

[53 FR 23872, June 24, 1988, as amended at 59 FR 63010, Dec. 7, 1994; 65 FR 2318, Jan. 14, 2000]

§ 878.4160 Surgical camera and accessories.

(a) *Identification.* A surgical camera and accessories is a device intended to be used to record operative procedures.

(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 § 878.9.

[53 FR 23872, June 24, 1988, as amended at 54 FR 13827, Apr. 5, 1989; 66 FR 38802, July 25, 2001]

§ 878.4165 Wound autofluorescence imaging device.

(a) *Identification.* A wound autofluorescence imaging device is a tool to view autofluorescence images from skin wounds that are exposed to an excitation light. The device is not intended to provide quantitative or diagnostic information.

(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 § 878.9.

[83 FR 52968, Oct. 19, 2018]

§ 878.4200 Introduction/drainage catheter and accessories.

(a) *Identification.* An introduction/drainage catheter is a device that is a flexible single or multilumen tube intended to be used to introduce nondrug fluids into body cavities other than blood vessels, drain fluids from body cavities, or evaluate certain physiologic conditions. Examples include irrigation and drainage catheters, pediatric catheters, peritoneal catheters (including dialysis), and other general surgical catheters. An introduction/drainage catheter accessory is intended to aid in the manipulation of or insertion of the device into the body. Examples of accessories include adaptors, connectors, and catheter needles.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in