

bag with adhesive, stomal bag, ostomy protector, and the ostomy size selector, but excludes ostomy pouches which incorporate arsenic-containing compounds.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[48 FR 53023, Nov. 23, 1983, as amended at 54 FR 25050, June 12, 1989]

**§876.5920 Protective garment for incontinence.**

(a) *Identification.* A protective garment for incontinence is a device that consists of absorbent padding and a fluid barrier and that is intended to protect an incontinent patient's garment from the patient's excreta. This generic type of device does not include diapers for infants.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.180, regarding general requirements concerning records, and §820.198, regarding complaint files.

[48 FR 53023, Nov. 23, 1983, as amended at 54 FR 25050, June 12, 1989]

**§876.5955 Peritoneo-venous shunt.**

(a) *Identification.* A peritoneo-venous shunt is an implanted device that consists of a catheter and a pressure activated one-way valve. The catheter is implanted with one end in the peritoneal cavity and the other in a large vein. This device enables ascitic fluid in the peritoneal cavity to flow into the venous system for the treatment of intractable ascites.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See §876.3.

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987]

**§876.5970 Hernia support.**

(a) *Identification.* A hernia support is a device, usually made of elastic, can-

vas, leather, or metal, that is intended to be placed over a hernial opening (a weakness in the abdominal wall) to prevent protrusion of the abdominal contents. This generic type of device includes the umbilical truss.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.180, regarding general requirements concerning records, and §820.198, regarding complaint files.

[48 FR 53023, Nov. 23, 1983, as amended at 59 FR 63010, Dec. 7, 1994]

**§876.5980 Gastrointestinal tube and accessories.**

(a) *Identification.* A gastrointestinal tube and accessories is a device that consists of flexible or semi-rigid tubing used for instilling fluids into, withdrawing fluids from, splinting, or suppressing bleeding of the alimentary tract. This device may incorporate an integral inflatable balloon for retention or hemostasis. This generic type of device includes the hemostatic bag, irrigation and aspiration catheter (gastric, colonic, etc.), rectal catheter, sterile infant gavage set, gastrointestinal string and tubes to locate internal bleeding, double lumen tube for intestinal decompression or intubation, feeding tube, gastroenterostomy tube, Levine tube, nasogastric tube, single lumen tube with mercury weight balloon for intestinal intubation or decompression, and gastro-urological irrigation tray (for gastrological use).

(b) *Classification.* (1) Class II (performance standards).

(2) Class I (general controls) for the dissolvable nasogastric feed tube guide for the nasogastric tube.

[49 FR 573, Jan. 5, 1984]

**PART 878—GENERAL AND PLASTIC SURGERY DEVICES**

**Subpart A—General Provisions**

Sec.

878.1 Scope.

878.3 Effective dates of requirement for premarket approval.