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## Title 21 —Food and Drugs

### Chapter I —Food and Drug Administration, Department of Health and Human Services

#### Subchapter H —**Medical Devices**

#### Part 876 —Gastroenterology-Urology Devices

#### Subpart F —Therapeutic Devices

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

**Source:** 48 FR 53023, Nov. 23, 1983, unless otherwise noted.

#### § 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 (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 § 876.9. The device 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, 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; 66 FR 38802, July 25, 2001]