Food and Drug Administration, HHS

§ 876.5900 Ostomy pouch and accessories.

(a) Identification. An ostomy pouch and accessories is a device that consists of a bag that is attached to the patient’s skin by an adhesive material and that is intended for use as a receptacle for collection of fecal material or urine following an ileostomy, colostomy, or ureterostomy (a surgically created opening of the small intestine, large intestine, or the ureter on the surface of the body).

(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.