

prevent excessive loss of water from the patient's blood. This highly permeable, semipermeable membrane may also permit greater loss of higher molecular weight substances from the blood, compared with the conventional dialyzer of the hemodialysis system and accessories (§ 876.5820). The extracorporeal blood system is the same generic type of extracorporeal blood system that is used in the hemodialysis system and accessories (§ 876.5820). The controlled dialysate delivery system also is similar to the conventional dialysate delivery system of the hemodialysis system and accessories (§ 876.5820), with the addition of an ultrafiltration controller to regulate the rate of the removal of water from the patient's blood and ensure that the pressure on the dialysate side of the membrane is always lower than on the blood side. This generic type of device includes the sealed dialysate delivery system.

(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]

**§ 876.5870 Sorbent hemoperfusion system.**

(a) *Identification.* A sorbent hemoperfusion system is a device that consists of an extracorporeal blood system similar to that identified in the hemodialysis system and accessories (§ 876.5820) and a container filled with adsorbent material that removes a wide range of substances, both toxic and normal, from blood flowing through it. The adsorbent materials are usually activated-carbon or resins which may be coated or immobilized to prevent fine particles entering the patient's blood. The generic type of device may include lines and filters specifically designed to connect the device to the extracorporeal blood system. The device is used in the treatment of poisoning, drug overdose, hepatic coma, or metabolic disturbances.

(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]

**§ 876.5880 Isolated kidney perfusion and transport system and accessories.**

(a) *Identification.* An isolated kidney perfusion and transport system and accessories is a device that is used to support a donated or a cadaver kidney and to maintain the organ in a near-normal physiologic state until it is transplanted into a recipient patient. This generic type of device may include tubing, catheters, connectors, an ice storage or freezing container with or without bag or preservatives, pulsatile or nonpulsatile hypothermic isolated organ perfusion apparatus with or without oxygenator, and disposable perfusion set.

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

**§ 876.5895 Ostomy irrigator.**

(a) *Identification.* An ostomy irrigator is a device that consists of a container for fluid, tubing with a cone-shaped tip or a soft and flexible catheter with a retention shield and that is used to wash out the colon through a colostomy, a surgically created opening of the colon on the surface of the body.

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

**§ 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). This generic type of device and its accessories includes the ostomy pouch, ostomy adhesive, the disposable colostomy appliance, ostomy collector, colostomy pouch, urinary ileostomy bag, urine collecting ureterostomy bag, ostomy drainage