§ 876.5665 The peritoneal dialysis system may regulate and monitor the dialysate temperature, volume, and delivery rate together with the time course of each cycle of filling, dwell time, and draining of the peritoneal cavity or manual controls may be used. This generic device includes the semiautomatic and the automatic peritoneal delivery system.

(2) The peritoneal access device is a flexible tube that is implanted through the abdominal wall into the peritoneal cavity and that may have attached cuffs to provide anchoring and a skin seal. The device is either a single use peritoneal catheter, intended to remain in the peritoneal cavity for less than 30 days, or a long term peritoneal catheter. Accessories include stylets and trocars to aid in the insertion of the catheter and an obturator to maintain the patency of the surgical fistula in the abdominal wall between treatments.

(3) The disposable administration set for peritoneal dialysis consists of tubing, an optional reservoir bag, and appropriate connectors. It may include a peritoneal dialysate filter to trap and remove contaminating particles.

(4) The source of dialysate may be sterile prepackaged dialysate (for semiautomatic peritoneal dialysate delivery systems or “cycler systems”) or dialysate prepared from dialysate concentrate and sterile purified water (for automatic peritoneal dialysate delivery systems or “reverse osmosis” systems). Prepackaged dialysate intended for use with either of the peritoneal dialysate delivery systems is regulated by FDA as a drug.

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

§ 876.5820 Hemodialysis system and accessories.

(a) Identification. A hemodialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that consists of an extracorporeal blood system, a conventional dialyzer, a dialysate delivery system, and accessories. Blood from a patient flows through the tubing of the extracorporeal blood system and accessories to the blood compartment of the dialyzer, then returns through further tubing of the extracorporeal blood system to the patient. The dialyzer has two compartments that are separated by a semipermeable membrane. While the blood is in the blood compartment, undesirable substances in the blood pass through the semipermeable membrane into the dialysate in the dialysate compartment. The dialysate delivery system controls and monitors the dialysate circulating through the dialysate compartment of the dialyzer.

(1) The extracorporeal blood system and accessories consists of tubing, pumps, pressure monitors, air foam or bubble detectors, and alarms to keep blood moving safely from the blood access device and accessories for hemodialysis (§ 876.5540) to the blood compartment of the dialyzer and back to the patient.

(2) The conventional dialyzer allows a transfer of water and solutes between the blood and the dialysate through the semipermeable membrane. The semipermeable membrane of the conventional dialyzer has a sufficiently low permeability to water that an ultrafiltration controller is not required to prevent excessive loss of water from the patient’s blood. This conventional dialyzer does not include hemodialyzers with the disposable inserts (Kiil type) (§ 876.5930) or dialyzers of high permeability (§ 876.5860).

(3) The dialysate delivery system consists of mechanisms that monitor and control the temperature, conductivity, flow rate, and pressure of
the dialysate and circulates dialysate through the dialysate compartment of
the dialyzer. The dialysate delivery
system includes the dialysate concen-
trate for hemodialysis (liquid or
powder) and alarms to indicate abnor-
mal dialysate conditions. This
dialysate delivery system does not in-
clude the sorbent regenerated dialysate
delivery system for hemodialysis
§876.5600), the dialysate delivery sys-
tem of the peritoneal dialysis system
and accessories (§876.5630), or the con-
trolled dialysate delivery system of the
high permeability hemodialysis system
§876.5860).
(4) Remote accessories to the
hemodialysis system include the
unpowered dialysis chair without a
scale, the powered dialysis chair with-
out a scale, the dialyzer holder set, di-
alysis tie gun and ties, and
hemodialysis start/stop tray.
(b) Classification. (1) Class II (per-
formance standards) for hemodialysis
systems and all accessories directly as-
associated with the extracorporeal blood
system and the dialysate delivery sys-
tem.
(2) Class I for other accessories of the
hemodialysis system remote from the
extracorporeal blood system and the
dialysate delivery system, such as the
unpowered dialysis chair, hemodialysis
start/stop tray, dialyzer holder set, and
dialysis tie gun and ties. The devices
subject to this paragraph (b)(2) are ex-
empt 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]
§ 876.5830 Hemodialyzer with dispos-
able insert (KiiI type).
(a) Identification. A hemodialyzer
with disposable inserts (KiiI type) is a
device that is used as a part of an arti-
ficial kidney system for the treatment
of patients with renal failure or tox-
emic conditions and that includes dis-
posable inserts consisting of layers of
semipermeable membranes which are
sandwiched between support plates.
The device is used with the
extracorporeal blood system and the
dialysate delivery system of the
hemodialysis system and accessories
§876.5820).
(b) Classification. Class II (per-
formance standards).
[48 FR 53023, Nov. 23, 1983, as amended at 53
FR 11253, Apr. 6, 1988]
§ 876.5860 High permeability
hemodialysis system.
(a) Identification. A high permeability
hemodialysis system is a device that is
used as an artificial kidney system for
the treatment of patients with renal
failure or toxemic conditions, and that
has a dialyzer with a semipermeable
membrane that is more permeable to
water than the semipermeable mem-
brane of the conventional dialyzer. The
device system consists of an
extracorporeal blood system, a high
permeability dialyzer, and a controlled
dialysate delivery system that incor-
porates an ultrafiltration controller to
prevent excessive loss of water from
the patient’s blood. This highly per-
meable, semipermeable membrane may
also permit greater loss of higher mo-
lecular 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 de-
ivery system also is similar to the con-
tventional dialysate delivery system
of the hemodialysis system and ac-
cessories (§876.5820), with the addition
of an ultrafiltration controller to regu-
late 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 de-
very system.
(b) Classification. Class III (premar-
ket 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 sys-
tem.
(a) Identification. A sorbent
hemoperfusion system is a device that