K961825

510(k) SUMMARY

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Telephone Number: **Fax Number:**	(847) 473-6081 (847) 473-6952
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Trade Name:	Ultra Set CAPD Disposable Disconnect Y-Set and 3L Ultra Set CAPD Disposable Disconnect Y-Set
Common Name:	Disconnect Y-Sets with solution drainage bag for Peritoneal Dialysis (PD)
Classification Name:	Peritoneal dialysis system and accessories per 21 CFR 876.5630
Equivalent Predicate:	Baxter CAPD Disposable Disconnect Y-Set (K902526) and UV-III Disposable Disconnect Y-Set (K883239).
Device Description:	The Y-shaped design of the set enables patients to initially drain the dialysis solution from the peritoneum into the attached drain bag and then to fill new dialysis solution from a solution container into the patient's peritoneum. The plastic Y-shaped configuration serves as a junction for three lengths of tubing. The first length of tubing is the patient connector and connects to the patient's transfer set via a luer lock connection. The second length of tubing has a spike connector for connection to the new solution container and an occlusion clamp which is utilized during the solution exchange. The third length of tubing has a empty drain bag and an occlusion clamp for collection of spent dialysate during the dialysis exchange.
Intended Use:	The Ultra Sets are designed for drainage and infusion of PD solution during a peritoneal dialysis exchange.

Summary of the technological characteristics compared to the predicate device:	In general, the design and materials of the subject disposable disconnect Y-sets are the same as the Baxter predicate devices. Differences in the subject Y-sets compared to the Baxter predicate devices consist of minor differences in the solution container and patient connections. Additionally, the drain bag on the 3L Ultra Set is five liters to accommodate larger effluent volumes.
Clinical Data:	Not applicable
Conclusions drawn from tests:	Components of the Ultra Set CAPD Disposable Disconnect Y-set and 3L Ultra Set CAPD Disposable Disconnect Y-set have previously met the USP XXII Class VI biological requirements and guidelines for safety screening of materials. The sets are gamma sterilized at the minimum sterilizing dose (msd) by a method determined and verified using Method 1 of the American National Standard Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) Guideline for radiation sterilization. The msd is between 14.3 and 25 kilogray (1.43-2.50 Mrad). The msd is audited quarterly. The testing specification for pyrogen evaluation detail the FDA guideline for the Limulus Amebocyte Lysate (LAL) Test. The sets are tested to an endotoxin limit of 0.5 EU/mL in accordance with the established limit for medical devices and as validated under FDA's "Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices", December 1987. Functional and physical testing are performed as in process and/or final inspections prior to release of product release ensuring a quality product.
Additional information requested by FDA:	None to date.

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