

K972579

510(k) SUMMARY

Submitter's name and Address:

David C. Ross, Pharm.D., MBA, RAC
Associate Director, Regulatory Affairs
Baxter Healthcare Corporation, Renal Division
1620 Waukegan Road
McGaw Park, IL 60085

OCT - 1 1997

Telephone Number:
Fax Number:

(847) 473-6081
(847) 473-6952

Contact:

David Ross

Trade Name:

High Dose Disconnect Cap and MiniCap with Povidone-Iodine Solution (5C4486) and High Dose Disconnect Cap with Povidone-Iodine Solution (5C4456)

Common Name:

Disconnect caps for Peritoneal Dialysis (PD) therapy

Classification Name:

Peritoneal dialysis system and accessories per 21 CFR 876.5630

Equivalent Predicate:

Baxter's Easy Lock™ Disconnect Cap with Povidone-Iodine Solution (K895631), Baxter's disconnect MiniCap with Povidone-Iodine Solution (K895631), and the Medionics QC Cap (K945567)

Device Description:

The High Dose Disconnect Cap and MiniCap with Povidone-Iodine Solution (5C4486) consists of the High Dose Disconnect Cap, which contains a povidone iodine impregnated polyurethane sponge, a spacer, and a MiniCap. The MiniCap also contains a povidone iodine impregnated polyurethane sponge. The povidone iodine sponge is used to disinfect the mating interface between the disconnect caps (High Dose Cap and MiniCap) and the patient connector of the PD disposable set and the patient transfer set, respectively. The High Dose Cap and the MiniCap are packaged together to conveniently allow the patient to disconnect from the peritoneal cyclor therapy when desired. The spacer aids in the convenience packaging of the two caps into one product and has no other functional use. The MiniCap product is currently cleared for marketing under K895631 and is sold separately.

K972579

Similarly, the High Dose Disconnect Cap with Povidone-Iodine Solution (5C4456) simply consists of the High Dose Disconnect Cap and a povidone iodine impregnated polyurethane sponge. The povidone iodine sponge is used to disinfect the mating interface between the disconnect cap and the patient connector of the PD disposable set.

Intended Use:

The High Dose Disconnect Cap and MiniCap with Povidone-Iodine Solution (5C4486) are single use caps that are intended for use with appropriate Peritoneal Dialysis (PD) products. The High Dose Disconnect Cap is designed to isolate (cap off) the Easy-Lock™ connector (patient line) of the PD disposable set. The MiniCap is designed to isolate (cap off) the Easy-Lock™ connector of the patient's transfer set.

The High Dose Disconnect Cap with Povidone-Iodine Solution (5C4456) is a single use cap that is intended for use with appropriate Peritoneal Dialysis (PD) disposable products. The High Dose Cap is designed to isolate (cap off) the Easy-Lock™ connector (patient line) of the PD disposable set.

Summary of the technological characteristics compared to the predicate device:

In general, the design and materials of the subject disposable disconnect caps are similar to the Baxter predicate devices. The caps provide an integral seal to the mating part, have exterior ribs to facilitate use, and contain a iodine impregnated sponge for disinfecting purposes.

Clinical Data:

Not applicable

Conclusions drawn from tests:

The performance/functional testing included microbiological, cap/connector seal, and ease of use (torque) testing. The data demonstrate that the High Dose Disconnect Cap was able to deliver the desired kill of the test organism. Additionally, the cap/connector seal passed the specified pressure test and the torque to remove the cap is not greater than currently available disconnect caps.

Additional information requested by FDA:

None to date.

David C. Ross
David C. Ross, Pharm.D., MBA, RAC
Associate Director, Regulatory Affairs

July 8, 1997
Date



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 1997

Mr. Robert L. Wilkinson, RAC
Director, Regulatory Affairs
Baxter Healthcare Corporation
1620 Waukegan Road
McGaw Park, Illinois 60085-6730

Re: K972579
High Dose Disconnect Cap and MiniCap with
Povidone-Iodine Solution (5C4486) and
High Dose Disconnect Cap with Povidone-Iodine
Solution (5C4456)
Dated: July 8, 1997
Received: July 10, 1997
Regulatory class: II
21 CFR §876.5630/Product code: 78 KDJ

Dear Mr. Wilkinson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Premarket Notification
High Dose Disconnect Cap and MiniCap with Povidone-Iodine Solution (5C4486) and
High Dose Disconnect Cap with Povidone-Iodine Solution (5C4456)

510(k) Number (if known): _____

Device Name: High Dose Disconnect Cap and MiniCap with Povidone-Iodine Solution (5C4486) and High Dose Disconnect Cap with Povidone-Iodine Solution (5C4456)

Indication for Use: The High Dose Disconnect Cap and MiniCap with Povidone-Iodine Solution (5C4486) are single use caps that are intended for use with appropriate Peritoneal Dialysis (PD) products. The High Dose Cap is designed to isolate (cap off) the Easy-Lock™ connector (patient line) of the PD disposable set. The MiniCap is designed to isolate (cap off) the Easy-Lock™ connector of the patient's transfer set.

The High Dose Disconnect Cap with Povidone-Iodine Solution (5C4456) is a single use cap that is intended for use with appropriate Peritoneal Dialysis (PD) disposable products. The High Dose Cap is designed to isolate (cap off) the Easy-Lock™ connector (patient line) of the PD disposable set.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Rathbone
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K972579

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use