DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2001

Ms. Elise Johnston
MOLDED PRODUCTS, Inc.
601 Durant Street
HARLAN IA 51537

Re: K010366
Trade/Device Name: Disposable Storage Caps
Regulation Number: 21 CFR §876.5820
Regulatory Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 FJI
Dated: August 23, 2001
Received: August 31, 2001

Dear Ms. Johnston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use:

The devices are used for capping off the two dialysate port connectors and the two blood port connectors of a hollow fiber dialyzer. Technicians use the devices during the cleaning, reprocessing, and disinfecting of the dialyzer. During the disinfecting procedure, the technician fills the dialyzer with a sterilant solution. The MPC Storage Caps prevent the large-scale leakage of the fluid stored inside the dialyzer. The MPC Storage Caps are also used to cap off the ports prior to disposal of the dialyzer.

The inside opening of the caps are tapered to match the standard port connections found on hollow fiber dialyzers (as specified in ISO Standard 8637: 1989). The friction seal created between the port and the cap prevents the leakage of stored fluids from the dialyzer.

The MPC vented port caps have a small vent in the top of the device. These vented caps are specifically for use with a sterilant solution known as Renalin. This sterilant is known to create pressure inside the dialyzer. The vented cap allows for relief of this pressure buildup.

Prescription Use ✓ OR Over-The-Counter-Use_____

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K010366