



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2002

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

Re: K022068
Trade/Device Name: Dialysate Tubing with Connectors
MPC-725 and MPC-740
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 FID
Dated: June 20, 2002
Received: June 25, 2002

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.

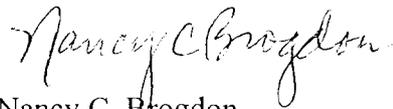
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) NUMBER (IF KNOWN):

DEVICE NAME: Dialysate Tubing with Connectors

INDICATIONS FOR USE:

MPC-740

The MPC-740 is a Male to Male Dialysate Connection Connector. It may be used to connect the MPC-725 to the Dialysis machine Dialysate Line in order to extend the length of the Dialysate Tubing. May also be used as a recirculation connector; connecting both dialysis machine Dialysate lines together.

MPC-725

The MPC-725 is a Female to Female Dialysate Connection Connector. When connected to the MPC-740 (which has been connected to the dialysis machines' dialysate line) this line may be used to extend the length of the Dialysis Machine Dialysate Line. The MPC-725 may also be used to connect one Dialyzer Port to another Dialyzer Port.

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

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use
 (Per 21 CFR 801.109)

OR

Over-The-Counter-Use

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, **Abdominal,**
and Radiological Devices

510(k) Number K023068