

16971991

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
K971991

NOV - 7 1997

A. Submitter Information:

Submitter Name: Bard Access Systems, Inc. (Division of C.R.
Bard, Inc.)
Address: 5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
Telephone Number: (801) 595-0700 ex 4982
Fax Number: (801) 595 4979
Contact Person: Jane Ann Martin
Date of Preparation: 5 November 1997

B. Device Name:

Common/Usual Name: Per-Q-Cath® Midline Catheters

Classification Name: Long-term Intravascular catheter (LJS)

C. Predicate Device Name:

Trade Name: Per-Q-Cath® Midline catheters

D. Device Description:

Per-Q-Cath midlines are silicone or polyurethane open-ended catheters in single or dual lumen configurations.

E. Intended Use:

For long term midline venous catheterization of selected intravenous infusates or blood therapy. A midline catheter placement is contraindicated for patients requiring solutions with final glucose concentrations above 10 percent and solutions with protein concentrations above 5 percent and patients requiring continuous infusion of vesicants.

F. Technological Characteristics Summary

This 510(k) does not involve any technological characteristic changes. This submission was to change the tip trimming instructions in the Instructions For Use only. No changes were made to the catheters.

G. Performance Data (if applicable)

No performance testing was done. A comparison of catheter tip trimming instructions from various competitors and a literature bibliography were sent to FDA to support the change in tip trimming instructions.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 1997

Ms. Jane Ann Martin
Regulatory Affairs Manager
Bard Access Systems, Incorporated
5425 West Amelia Earnhart Drive
Salt Lake City, Utah 84116

Re: K971991
Trade Name: Gesco Per-O-Cath® Midline Catheters
Regulatory Class: II
Product Code: FOZ
Dated: August 7, 1997
Received: August 11, 1997

Dear Ms. Martin:

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 (Pre-market 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 pre-market notification submission does not affect any obligation you might have under sections 531

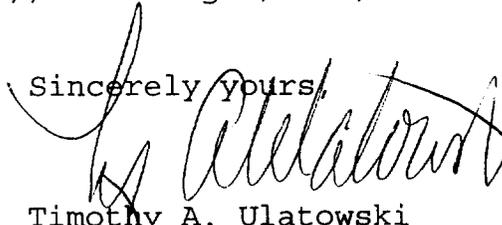
Page 2 - Ms. Martin

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) 594-4618. 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,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

- Enclosure

INDICATION(S) STATEMENT*

K971991

I state in my capacity as Regulatory Affairs Manager of Bard Access Systems, that this notification (510(k)) for the following device, **Per-Q-Cath® Midline Catheters**, are indicated for the following:

Per-Q-Cath® Midline Catheters are indicated for short or long term peripheral access to the peripheral venous system for selected intravenous therapies and blood sampling. A midline catheter is contraindicated for patients requiring solutions with final glucose concentrations above 10 percent and solutions with protein concentrations above 5 percent and patients requiring continuous infusion of vesicants.



Signature of 510(k) Submitter

Jane Ann Martin

Printed Name of Submitter

6 Nov 97

Date

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.



(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K971991

Prescription Use
(Per 21 CFR 801.109)