SEP 16 1998

I. 510(k) SUMMARY

Submitted By:
Neal E. Fearnot, President
MED Institute, Incorporated
West Lafayette, Indiana 47906
(765) 463-7537
July 16, 1998

Device:

Trade Name:	Mini Polyurethane Catheter
Common/Usual Name:	Implanted Subcutaneous Intravascular Catheter
Proposed Classification:	Implanted Subcutaneous Intravascular Catheter

Predicate Devices:
The Mini Polyurethane has the same intended use, design, and materials of construction as predicate catheters supplied with Vital-Port® systems manufactured by COOK Vascular™ Incorporated.

Device Description:
The Mini Polyurethane Catheter is for use in patient therapy requiring long-term vascular access for infusion therapy and/or blood sampling. The device is supplied sterile and is intended for one-time use. The construction materials comprising the Mini Polyurethane Catheter are identical to those used in predicate Vital-Port® system catheters. Reasonable assurance of biocompatibility of the materials comprising this device is provided by their established history of use in medical product manufacturing.

Substantial Equivalence:
The Mini Polyurethane Catheter will be manufactured according to specified process controls and a Quality Assurance Program, undergoing packaging and sterilization procedures similar to devices currently marketed and distributed by COOK Vascular™ Incorporated. This device is similar with respect to indications for use, materials and physical construction to predicate devices in terms of section 510(k) substantial equivalency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 1998

Mr. Neal E. Fearnot
President
MED Institute, Incorporated
A Cook Group Company
P.O. Box 2402
West Lafayette, Indiana 47906

Re: K982507
Trade Name: Mini Polyurethane Catheter
Regulatory Class: Unclassified
Product Code: LJT
Dated: July 16, 1998
Received: July 20, 1998

Dear Mr. Fearnot:

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 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). 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 requirements, 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) 594-4692. 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"(21CFR 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/dsma/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

510(k) Number (if known): K982507

Device Name: Mini Polyurethane Catheter

Indications For Use:

The Mini Polyurethane Catheter is intended for use with single-chamber Vital Port® reservoirs for use in patient therapy requiring long-term vascular access for infusion therapy and/or blood sampling.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K982507

Prescription Use 1
(Per 21 CFR 801.109)

OR

Over-The-Counter Use 3

(Optional Format 1-2-96)