K971140

G. 510(K) SUMMARY

NOV 17 1997

Submitted By:

Neal E. Fearnot, Ph.D., E.E.
President
MED Institute, Incorporated
P.O. Box 2402
West Lafayette, IN 47906
(765) 463-7537
March 27, 1997

Device:

Trade Name:	Vital-Port® Infusion Pal™
Common/Usual Name:	Locating Ring, Port Stabilizer
Proposed Classification Name:	Vein Stabilizer 21CFR §880.6980 (80LBJ) with intended use specific to implanted subcutaneous intravascular catheters (80LJT)

Predicate Devices:

The Vital-Port® Infusion Pal™ is similar to predicate vein stabilizers that are currently marketed in terms of technological characteristics and the same intended use of facilitating location and stabilization for vessel access. The Vital-Port® Infusion Pal™ is used with totally implantable vascular access systems for indirect vessel access.

Device Description:

The Vital-Port® Infusion Pal™ is an open-ringed plastic disk that is intended to facilitate locating and stabilizing the port body for accessing Vital-Port® Vascular Access Systems. The Vital-Port® Infusion Pal™ is placed on the skin surface on the area overlying the port septum. The device is supplied sterile and intended for one-time use.

Substantial Equivalence:

The Vital-Port® Infusion Pal™ will be manufactured according to specified process controls and a Quality Assurance Program, undergoing manufacturing, packaging and sterilization procedures similar to devices currently manufactured, marketed and distributed by Cook Vascular Incorporated. This device is similar with respect to indications for use and technology 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

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Neal E. Fearnot, Ph.D.,E.E.
President
Med Institute, Incorporated
P.O. Box 2402
West Lafayette, Indiana 47906

Re: K971140
Trade Name: Vital-Port Infusion Pal
Regulatory Class: Unclassified
Product Code: LJT
Dated: October 10, 1997
Received: October 14, 1997

Dear Dr. 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 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) 594-4618. 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

510(k) Number (if known): K97#### K971140

Device Name: **VITAL-PORT® INFUSION PAL™**

Indications For Use:

The Vital-Port® Infusion Pal™ is intended to facilitate locating and stabilizing the port body for accessing the portal septum of a Vital-Port® Vascular Access System.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Roberta Cucceste

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

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)