

MAY 20 1997

K970690

I. 510(K) SUMMARY

Submitted By:

Neal E. Fearnot, Ph.D., E.E.
President
MED Institute, Incorporated
P.O. Box 2402
West Lafayette, IN 47906
(317) 463-7537
February 24, 1997

Device:

Trade Name:	Locking Stylet 2
Common/Usual Name:	Stylet, Wire Guide Stylet, Catheter Retrieval Device
Proposed Classification Name:	Predicate devices of this type with similar intended uses have been classified into Class I or Class II.

Predicate Devices:

The Locking Stylet 2 is similar to the predicate Locking Wire Guide Stylet that is currently marketed with respect to intended use, material composition, and method of operation.

Device Description:

The Locking Stylet 2 is used during the percutaneous removal of cardiac leads, indwelling catheters and other foreign objects having a central lumen. The device is supplied sterile and is intended for one-time use. Reasonable assurance of biocompatibility of the materials comprising the Locking Stylet 2 is provided by their established history of use in medical product manufacturing by COOK Vascular™ Incorporated.

Substantial Equivalence:

The Locking Stylet 2 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1997

Neal E. Fearnot, Ph.D.
President
MED Institute, Inc.
A Cook Group Company
1400 Cumberland Avenue
West Lafayette, Indiana 47906

Re: K970690
Locking Stylet 2
Regulatory Class: II (two)
Product Code: DQX
Dated: February 24, 1997
Received: February 25, 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 (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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4648. 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 at (301) 443-6597.

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

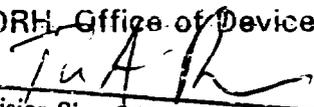
Device Name: Locking Stylet 2

Indications For Use:

The Locking Stylet 2 is intended for use during the percutaneous removal of cardiac leads, indwelling catheters and other foreign objects having a central lumen.

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

Concurrence of CDRL Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970690

Prescription Use ↓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)