MAY 26 1998

510(K) SUMMARY

March 20, 1998

K981061

Submitted By: Neal Fearnot, Ph.D.
President
MED Institute, Incorporated
1400 Cumberland Ave.
West Lafayette, IN 47906

Device Name	DC#
Byrd Dilator Sheath Set - Polypropylene	K893480
Byrd Dilator Sheath Set - Teflon	K902469
Byrd Stainless Steel Dilator Sheath	K902502
Byrd Workstation	K902477 K914555
Byrd Telescoping Stainless Steel Dilator Sheath Set	K922354
Needle's Eye Snare	K961992

Device Description and Intended Use: The devices consist of sheaths and snares intended for use in patients requiring the percutaneous dilation of tissue surrounding cardiac leads, indwelling catheters, and foreign objects, and/or in patients requiring the retrieval of cardiac leads, indwelling catheters, fragments of catheter tubing or wire guides, and other foreign objects.

Predicate Devices	DC#
Metal Reinforced Flexible Dilator Sheath	K945586
Wilkoff Locking Stylet	K970690

Substantial Equivalence: The 510(k) submission serves to notify FDA of labeling revisions made to previously cleared devices. No changes have been made to the devices; they are substantially equivalent to the predicate devices, having the same intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 26 1998

Neal Fearnot, Ph.D.
President
MED Institute, Inc.
A Cook Group Company
P.O. Box 2402
West Lafayette, IN 47906

Re: K981061
Trade Name: Byrd Dilator Sheath Set-Polypropylene
Regulatory Class: II
Product Code: GCC

Trade Name: Byrd Dilator Sheath Set-Teflon
Regulatory Class: II
Product Code: GCC

Trade Name: Byrd Stainless Steel Dilator Sheath
Regulatory Class: II
Product Code: DRE

Trade Name: Workstation Intravascular Retrieval Set
Regulatory Class: II
Product Code: DRE

Trade Name: Byrd Telescoping Stainless Steel Dilator Sheath Set
Regulatory Class: II
Product Code: GCC

Trade Name: Needle's Eye Snare
Regulatory Class: II
Product Code: DXE
Dated: March 20, 1998
Received: March 23, 1998

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 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) 594-4648. 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"(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,

Thomas J. Callahan

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

Enclosure

510(k) Number (if known): K98 1061

Device Name: Byrd Dilator Sheath Set - Polypropylene or Teflon
Indications For Use: The Byrd Dilator Sheath Set is intended for use in patients requiring the percutaneous dilation of tissue surrounding cardiac leads, indwelling catheters and foreign objects.

Device Name: Byrd Stainless Steel Dilator Sheath
Indications For Use: The Byrd Stainless Steel Dilator Sheath is intended for use in patients requiring the percutaneous dilation of tissue surrounding cardiac leads, indwelling catheters and foreign objects.

Device Name: Byrd WORK STATION™
Indications For Use: The Byrd WORK STATION™ is intended for use in patients requiring the percutaneous retrieval of cardiac leads, indwelling catheters, fragments of catheter tubing or wire guides, and other foreign objects.

Device Name: Byrd Telescoping Stainless Steel Dilator Sheath Set
Indications For Use: The Byrd Telescoping Stainless Steel Dilator Sheath Set is intended for use in patients requiring the percutaneous dilation of tissue surrounding cardiac leads, indwelling catheters and foreign objects.

Device Name: NEEDLE'S EYE™ Snare
Indications For Use: The NEEDLE'S EYE™ Snare is intended for use in patients requiring the percutaneous retrieval of indwelling catheters, cardiac leads, fragments of catheter tubing or wire guides, and other foreign objects.

(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 Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

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