

NOV 12 1997

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

The design, use and function of the 1.4 Fr MAPCath sensor stylet described in this pre-market notification are substantially equivalent (same product) to the 1.4 Fr sensor stylet described in Bard Access Systems submission K935380 and substantially equivalent in design, use and function to the Navion SMART-WIRE sensor described in submission K901263.

A table comparing the physical features of the proposed 1.4 Fr MAPCath sensor stylet to the one that received concurrence under K935380 and the original sensor stylet in K901263 is shown in Exhibit 6.

The 510(k) "Substantial Equivalence Decision-Making Process" decision tree (exhibit 7) was used to make the substantial equivalence determination. The decision tree questions and answers are as follows:

1.0 *Does the new device have same indication statements?*

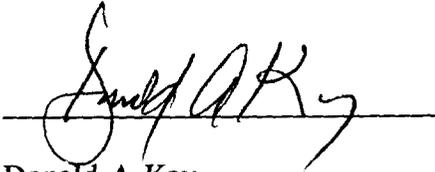
Yes. The sensor stylet described in this 510(k) submission has the same indications for use as the current Navion MAPCath (SMART-WIRE) sensor stylet and the current Bard Access Systems sensor stylet. They are designed, when used in conjunction with the catheter locator instrument, to aid in the placement of central venous catheters by providing real-time information as to the position of the catheter inside the body during the catheter insertion procedure

2.0 *Does new device have same technological characteristics, e.g., design, material, etc.?*

Yes. The sensor stylet described in this 510(k) submission is the same product described in Bard Access Systems 510(k) (reference K935380).

3.0 *Are the descriptive characteristics precise enough to ensure equivalence?*

Yes. The sensor stylet described in this 510(k) submission is the same product that received concurrence under K935380.

A handwritten signature in black ink, appearing to read "Donald A. Kay", is written over a horizontal line.

Donald A Kay
President, Navion Biomedical Corp.



NOV 12 1997
Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Donald A. Kay
President
Navion Biomedical Corporation
312 Tosca Drive
Stoughton, Massachusetts 02072

Re: K973057
Trade Name: 1.4 Fr MAPcath Sensor Stylet
Regulatory Class: Unclassified
Product Code: LJS
Dated: August 7, 1997
Received: August 15, 1997

Dear Mr. Kay:

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.

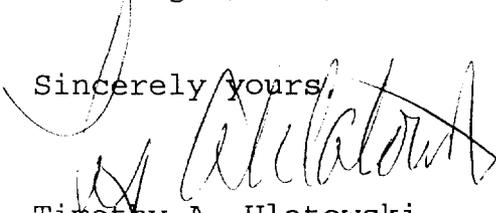
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the 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.

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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" (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): K973051

Device Name: 1.4 FR MAPCATH SENSOR STYLET

Indications For Use:

The 1.4 Fr MAPCath Sensor Stylet is designed to be used with the NAVIGATOR catheter locator instrument to aid in the placement of central venous catheters (CVCs) by indicating the position and direction of the CVC tip inside the body during the catheter insertion procedure.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucente

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K973051

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)