Section 2 - 510(k) Summary and Certification

[As required by 21 CFR 807.92(c)]

1. Submitter's Name / Contact Person

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2. General Information

Trade Name	NeuroVasx Sub-Microinfusion Catheter
Classification Name	Diagnostic Intravascular Catheter
Classification:	This device has been classified by the Circulatory Systems Device Panel into Class II, (21 CFR 870.1200).
Identification of Equivalent Device	• In-Time™ Intravascular Infusion Catheter; Boston Scientific Corporation / SciMed Life Systems (K963988) • Segue™ Infusion Catheter; Interventional Innovations Corporation (K964154) • Mach-16 Nitinol Guidewire; Target Therapeutics (K862983)

3. Device Description

The NeuroVasx Sub-Microinfusion Catheter is a single use, 1.4 Fr device designed to fit within a standard microcatheter for advancement to, and navigation of a lesion site. A nitinol mandrel within the NeuroVasx catheter lumen facilitates axial movement and stability during navigation. The catheter is designed to infuse liquid diagnostic agents radially through side holes in the wall of the catheter to improve the diffusion and mixing of the infused agent with the blood flow.

The NeuroVasx catheter is contained in a plastic hoop assembly and sealed in a Tyvek / polyester pouch. The sealed pouch assembly is labeled and placed in a shelf carton along with the instructions for use, and then sterilized in a gamma radiation sterilization process.

4. Intended Use

The NeuroVasx Sub-Microinfusion Catheter is intended for the delivery of diagnostic agents into the neurovasculature.

5. Technological Characteristic Comparisons

The NeuroVasx Sub-Microinfusion Catheter is substantially equivalent to the Boston Scientific Corporation / Target Therapeutics In-Time™ Intravascular

Infusion Catheter (K963988), the Interventional Innovations Corporation Segue™ Infusion Catheter (K964154) and the Mach-16 Nitinol Guidewire; Target Therapeutics (K862983). Compared to these predicate devices, the NeuroVasx catheter has similar intended use (delivery of liquid agents into the vascular system) and is constructed of the same or substantially equivalent materials (high density polyethylene, nitinol wire, polycarbonate hub). The NeuroVasx catheter sizes are comparable as are the infusion pressures.

6. *Summary of Studies*

Design verification testing was performed to verify that the NeuroVasx catheter met the design specifications and performance requirements. The results of the comparative and design verification testing confirmed that the NeuroVasx catheter performs as well or better than the predicate devices tested and is suitable for use; no new questions of safety and effectiveness were raised. Confirmatory biocompatibility testing was performed on the materials used in the construction of the NeuroVasx catheter. All materials passed biocompatibility testing and are suitable for this application.

7. *Substantial Equivalence Comparison*

The NeuroVasx Sub-Microinfusion Catheter is substantially equivalent to the following products:

In-Time™ Intravascular Infusion Catheter	Segue™ Infusion Catheter	Mach-16 Nitinol Guidewire
Boston Scientific Corp / SciMed Life Systems 6655 Wedgewood Road Maple Grove, MN 55311	Interventional Innovations Corp. 2670 Patton Road St. Paul, MN 55113	Target Therapeutics 2100 South Sepulveda Blvd Los Angeles, CA 90025
Premarket Notification Number: K963988	Premarket Notification Number: K964154	Premarket Notification Number: K862983

8. *Conclusion (statement of equivalence)*

The data and information provided in this submission supports a substantial equivalence determination, and, therefore, 510(k) premarket notification clearance of the NeuroVasx Sub-Microinfusion Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 1999

Mr. Jeffrey A. Lee
President/Chief Executive Officer
NeuroVasx, Inc.
2355 Polaris Lane North, Suite 116
Plymouth, Minnesota 55447

Re: K984258
Trade Name: Neuro Vasx Sub-Microinfusion Catheter
Regulatory Class: II
Product Code: JCY
Dated: November 25, 1998
Received: November 30, 1998

Dear Mr. Lee:

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) 594-4595. 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

The NeuroVasx Sub-Microinfusion Catheter is intended for the delivery of diagnostic agents into the neurovasculature.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984258

Prescription Use
(Per 21 CFR 801.109)