JAN 27 1999

K972065

510(k) Summary

General Information

Classification	Class II
Trade Name	AURORA™ Guide Catheter
Submitter	Neurovena 1879 Buerkle Road White Bear Lake, MN 55110 (612) 777-3700
Contact	Jim Segermark Vice President

Intended Use

The AURORA is intended to provide a pathway through which a physician can introduce therapeutic devices into the general and neurovasculature.

Predicate Devices

FasGuide Catheter from Target Therapeutics, Inc.

Device Description

The AURORA is a single lumen radiopaque catheter with a proximal Luer fitting. The AURORA is pakaged sterile and is intended for single use only.

Materials

All materials used in the manufacture of the AURORA are biocompatible and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification. Testing included flow rate, torque, static pressure, bond strength and demensional equivalence.

Summary of Substantial Equivalence

The AURORA is equivalent to the predicate productfrom Target Therapeutics. The clinical indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent. Neurovena believes the AURORA Guide Catheter is substantially equivalent to existing marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 1999

Ms. Ann Quinlan-Smith
Vice President, Quality Assurance and Regulatory Affairs
Microvena Corporation
1861 Buerkle Road
White Bear Lake, Minnesota 55110

Re: K972065
Trade Name: MICROVENA Aurora™ Guide Catheter
Regulatory Class: II
Product Code: DQY
Dated: November 23, 1998
Received: November 24, 1998

Dear Ms. Quinlan-Smith:

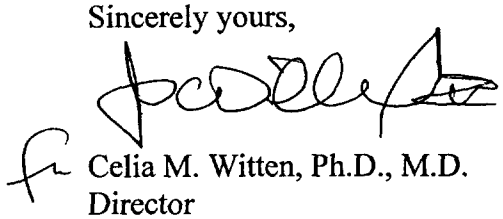
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



for 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

K972065

Indications for Use

510(k) Number (if known):	This application
Device Name:	AURORA Guide Catheter
Indications for Use:	Intended to provide a pathway through which a physician can introduce therapeutic devices into the general and neurovasculature.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use _ (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972065