JUN 16 1999

K991898

Special 510(k) Summary

HyTek™ Guidewire

(Prepared in accordance with 21 CFR part 807.92)

510(k) Number: This application

1. Submitter: Prepared and Submitted by:
MICROVENA Corporation
Angela Mallery
Sr. Regulatory Affairs Associate
651-7777-6700
1861 Buerkle Road
White Bear Lake, MN 55110

2. Device Name: Guidewire
Trade Name: HyTek Guidewire
Classification Name: Wire, Guide, Catheter
Classification Code: 74 DQX

3. Substantial Equivalency: The HyTek guidewire is substantially equivalent to K943390 and K991194.

4. Device Description and Intended Use:
The MICROVENA HyTek Guidewire is designed to fit inside a catheter, for the purpose of directing the catheter through a blood vessel.

The main body of the guidewire is constructed of Nitinol. The distal tip is a helical coiled wire wound around the inner core. The guidewire is coated with a hydrophilic coating to help facilitate smoother passage.

The HyTek Guidewire is available in diameters of .014" to .035, and in lengths from 80 cm to 300 cm.

5. Technological Characteristics
MICROVENA's HyTek guidewire have the same indications for use and are otherwise technically the same as the predicate device.

6. Non-Clinical Tests
The results of these tests demonstrated the functionality and performance characteristics of the guidewire are comparable to the currently marketed device. These tests included: torque, flexibility, and coating adherence.

7. Conclusions
Based on information presented in this 510(k) premarket notification, MICROVENA guidewires are considered substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 1999

Ms. Angela Mallery
Sr. Regulatory Affairs Associate
MICROVENA Corporation
1861 Buerkle Road
White Bear Lake, MN 55110

Re: K991898
Trade Name: HyTek™ Guidewire
Regulatory Class: II
Product Code: DQX
Dated: June 3, 1999
Received: June 4, 1999

Dear Ms. Mallery:

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) 594-4586. 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.
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):	This application
Device Name:	HyTek Guidewire
Indications for Use:	The 0.035" and 0.025" Hytek guidewire is indicated for use in the peripheral vasculature. The 0.014". 0.016", and 0.018" HyTek Guidewires are indicated for use in the peripheral and coronary vasculature.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christy M-A for Callahan

(Division Sign-Off)

Division of Cardiovascular, Respiratory, Neurological Devices

510(k) Number K991898

Prescription Use
(Per 21 CRF 801.109)

OR

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