MICROVENA CORPORATION

K971984

510(k) Summary

SEP 19 1997

Contact/Submitter:	Janell Colley, Regulatory Affairs Associate
Date Prepared:	September 8, 1997
Trade Name:	The Amplatz Thrombectomy Device
Common Name:	Thrombectomy Catheter
Classification Name:	Percutaneous Catheter (per 21 CFR 870.1250)
Predicate Devices:	MICROVENA Amplatz Thrombectomy Device
Device Description:	The Amplatz Thrombectomy Device (ATD) is a percutaneous, rotational thrombectomy device consisting of a polyurethane catheter. Inside the catheter, a distal rotor housing contains a small diameter, recessed impeller, attached to a drive shaft. The shaft is connected to a disposable, high speed, air driven motor. An infusion line with luer connector, attached to the proximal motor assembly, allows for infusion of saline through the catheter. A foot pedal/regulator assembly is required to operate the air motor.
Intended Use:	The modified Amplatz Thrombectomy Device (ATD) is intended for use in the mechanical dissolution of acute and sub-acute thrombus within dialysis fistulae.
Functional/Safety Testing:	The modified Amplatz Thrombectomy Device (ATD) device has successfully undergone functional and safety testing of new design features, including joint strengths, flow rate tests, burst tests, flexibility tests, device life tests, maceration capability tests, and material biocompatibility tests.
Conclusion:	The modified Amplatz Thrombectomy Device (ATD) is substantially equivalent to the predicate device.

1861 Buerkle Road ▲ White Bear Lake, Minnesota 55110-5246
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 ...

Ms. Janell Colley
Microvena Corporation
1861 Buerkle Road
White Bear Lake, Minnesota 55110-5246

Re: K971984
Amplatz Thrombectomy Device
Regulatory Class: II (two)
Product Code: 74 MCW
Dated: September 5, 1997
Received: September 9, 1997

Dear Ms. Colley:

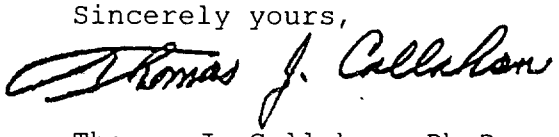
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4639. 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,



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):	K971984
Device Name:	Amplatz Thrombectomy Device
Indications for Use:	The intended use for the device is the mechanical dissolution of acute and sub-acute thrombus within dialysis fistulae.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
Neurological Devices
510(k) Number K971984

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-the-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)