

NOV 18 1998

1C982657

510(k) Summary

510(K) SUMMARY

SUBMITTER: MICROVENA Corporation

CONTACT PERSON: Tonya Weigel
MICROVENA Corporation
1861 Buerkle Road
White Bear Lake, MN 55110

DATE PREPARED: July 29, 1998

TRADE NAME: Amplatz Thrombectomy Device

CLASSIFICATION NAME and NUMBER: Peripheral Atherectomy Catheter
Class II, 21 CFR 870.4875

PRODUCT CODE: 74MCW

PREDICATE DEVICE(S): MICROVENA Corporation's Amplatz Thrombectomy Device

DEVICE DESCRIPTION: The Amplatz Thrombectomy Device (ATD) is a percutaneous, thrombectomy device consisting of a catheter, a small diameter impeller encased in a distal housing, and a driveshaft. The driveshaft is the connection between the impeller and a disposable, high speed, air driven motor. An infusion line with luer connector, attached to the proximal motor housing, allows infusion of saline. A foot pedal/regulator assembly is required to operate the air motor.

INTENDED USE: The Amplatz Thrombectomy Device (ATD) is intended for use in the mechanical dissolution of acute and subacute thrombus within dialysis fistulae.

FUNCTIONAL & SAFETY TESTING: The Amplatz Thrombectomy Device (ATD) device has successfully undergone functional and safety testing of new design features, including joint strengths, flow rate tests, flexibility tests, and material biocompatibility tests.

CONCLUSION: The Modified Amplatz Thrombectomy Device (ATD) is substantially equivalent to the Predicate ATD.



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Ms. Tonya L. Weigel
Regulatory Affairs Associate
MICROVENA Corporation
1861 Buerkle Road
White Lake, MN 55110-5246

Re: K982657
Trade Name: Amplatz Thrombectomy Device
Regulatory Class: II
Product Code: MCW
Dated: October 27, 1998
Received: October 28, 1998

Dear Ms. Weigel:

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, Ph.D.

Director

Division of Cardiovascular, Respiratory
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

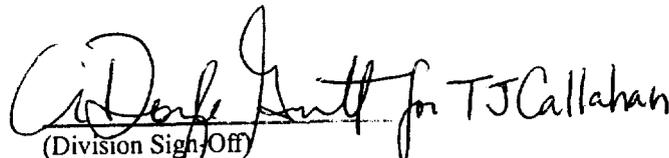
510(k) Number (if known): K98 2657

Device Name: Amplatz Thrombectomy Device

Indications for Use:

The Amplatz Thrombectomy Device is intended for use in the mechanical dissolution of acute and subacute thrombus within dialysis fistulae.

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign Off)
Division of Cardiovascular, Respiratory
and Neurological Devices
510(k) Number K98 2657/