



MAR - 6 1998

510(k) SUMMARY

Contact/Submitter: Janell Colley, Regulatory Affairs Associate

Date Prepared: January 13, 1998

Trade Name: The Amplatz Goose Neck Snare

Common Name: Intravascular Retrieval Device

Classification Name: Percutaneous Retrieval Device

Predicate Devices: MICROVENA Amplatz Goose Neck Snare
Premarket Notification K901502

Device Description: The Amplatz Goose Neck Snare consists of a braided nitinol loop attached to a solid core nitinol guidewire. The plane of the loop is perpendicular to the host wire. The loop is covered with a gold-plated tungsten coil to enhance radiopaque. The shaft of the snare consists of a solid continuous Nitinol core wire shaft. The loop snare is delivered in a multi-purpose catheter. The catheter has a radiopaque marker band at its distal tip.

The package configuration consists of a compact spiral configuration, using hoops to contain the snare and catheter. These spiral hoops are then double pouched in Tyvek/mylar pouches.

Intended Use: The Amplatz Goose Neck Snare is a Class II device intended for use in the cardiovascular system or hollow viscous to retrieve and manipulate foreign objects. Manipulation procedures include indwelling venous catheter repositioning, indwelling venous catheter fibrin sheath stripping, and central venous access venipuncture procedure assistance. The Amplatz Goose Neck Snare received clearance for market based on functional and safety testing detailed in the original premarket notification K901502.

Conclusion: The Amplatz Goose Neck Snare is substantially equivalent to the predicate devices based on design and indications for use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 1998

Ms. Janell Colley
Regulatory Affairs Associate
Microvena Corporation
1861 Buerkle Road
White Bear Lake, MN 55110-5246

Re: K972511
Amplatz Goose Neck Snare Kit/Catheter
Regulatory Class: II (two)
Product Code: 74 DXE
Dated: January 13, 1998
Received: January 14, 1998

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.

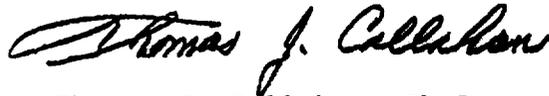
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice 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.

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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) 594-4648. 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: K972511

Device Name: Amplatz Goose Neck Snare

Indications for Use: The Amplatz Goose Neck Snare is a Class II device intended for use in the cardiovascular system or hollow viscous to retrieve and manipulate foreign objects. Manipulation procedures include indwelling venous catheter repositioning, indwelling venous catheter fibrin sheath stripping, and central venous access venipuncture procedure assistance.

T. R.

(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K972511

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)