JUN 10 1998

K970668

510(k) SUMMARY

SUBMITTER:	MICROVENA Corporation
CONTACT PERSON:	Ms. Christine M. Busch Regulatory Affairs Associate
DATE PREPARED:	February 13, 1997
TRADE NAME:	*Amplatz "GOOSE NECK" Microsnare*
CLASSIFICATION NAME:	Catheter, Percutaneous 21 CFR 870.1250
PRODUCT CODE:	78 DQY
PREDICATE DEVICE(S):	Amplatz "GOOSE NECK" Microsnare (K925439) Target Therapeutics' Retrieval Device(s): Retriever-18 (K914067), Retriever-10 (K921649)

DEVICE DESCRIPTION: The Amplatz "GOOSE NECK" Microsnare is a percutaneous retrieval and manipulation device with a uniquely shaped retriever loop. The "GOOSE NECK" Microsnare component consists of a core wire, with the "beak-like" retriever loop mounted at a right angle to the axis of shaft at its distal tip. The device is primarily comprised of a nickel-titanium alloy allowing virtual kink-resistant performance during navigation and retrieval of a foreign object.

INTENDED USE: The Amplatz "GOOSE NECK" Microsnare is intended for use as a tool to retrieve and manipulate foreign bodies from distal peripheral vessels of the cardiovascular system and hollow viscus. This* includes intravascular foreign objects such as coils, balloons, portions of catheter and/or guidewires misplaced during interventional radiological procedures within the peripheral, neuro and cardiovasculature.

FUNCTIONAL & SAFETY TESTING: The Amplatz "GOOSE NECK" Microsnare has successfully passed all functional and safety testing requirements.

CONCLUSION: The Amplatz "GOOSE NECK" Microsnare is deemed substantially equivalent to commercially available MICROVENA and Target Therapeutics Retrieval devices based on functional testing and published clinical experiences.

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* As defined per Stedman's Medical Dictionary, Twenty-Third Edition; page 1563: ***viscus,*** pl. **viscera** (vis'kus, vis'er-ah) [L. the soft parts, internal organs. VISC-] An organ of the digestive, respiratory, urogenital, and endocrine systems as well as the spleen, the heart and great vessels; hollow and multilayered walled organs studied in splanchology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 10 1998

Ms. Doralie Poganski
Neurovascular Project Manager
Microvena Corporation
1861 Buerkle Road
White Bear Lake, Minnesota 55110-5246

Re: K970668
Trade Name: The Amplatz "Goose Neck" MicroSnare (NEUROSnare)
Regulatory Class: II
Product Code: DQY
Dated: March 13, 1998
Received: March 16, 1998

Dear Ms. Poganski:

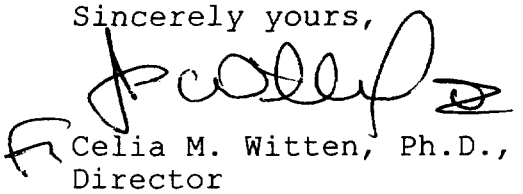
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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

510(k) Number (if known): K970668

Device Name: The Amplatz "Goose Neck" MicroSnare (NEUROSnare)

Indications For Use:

The Amplatz Goose Neck MicroSnare (NEUROSnare) is intended for use in the retrieval and manipulation of atraumatic foreign bodies located in the cornary and peripheral cardiovascular system and the extra-cranial neurovascular anatomy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510 (k) Number K970668

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)