510(k) Summary

K082385

Trade Name: Chaperon Guiding Catheter System

Generic Name: Percutaneous Catheter

DEC 11 2008

Classification: Class II, 21 CFR 870.1250

Submitted By: MicroVention, Inc
75 Columbia
Aliso Viejo, California U.S.A.

Contact: Florin Truuvert

Predicate Device:

Number	Description	Predicate For	Clearance Date
K070970	Penumbra Inc., Neuron Intracranial Access System	Chaperon Guiding Catheter System	August 17, 2007

Device Description

The Chaperon Guiding Catheter system is designed to advance interventional and diagnostic devices through the vasculature. The device is intended for general intravascular use, including the neuro and peripheral vasculature. The Chaperon Guiding Catheter is a two-catheter system comprised of the outer catheter and the inner catheter. The Chaperon Guiding Catheter system can be used individually with 0.035 in or a 0.038 in guidewire or together with the Inner Catheter to access the desired anatomy.

Indication For Use

Chaperon Guiding Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries.

Verification and Test Summary Table

Bench Testing	Result
Surface Contamination & Tip Configuration	Met established criteria
Dimensional Inspection & Physical Attributes	Met established criteria
Tensile Strength	Met established criteria
Hub Attachment Strength	Met established criteria
Tip Attachment Strength	Met established criteria
Freedom from Leakage – Fluid & Air	Met established criteria
Leak Test (High Static Pressure)	Met established criteria
Hub Gauging	Met established criteria
Separation Force	Met established criteria
Stress Cracking	Met established criteria
Screwing Torque	Met established criteria
Ease of Assembly	Met established criteria
Resistance to Overriding	Met established criteria
Flow Rate	Met established criteria
Radio-Detectability	Met established criteria
Catheter Burst & Leakage	Met established criteria
Stiffness & Kink Resistance	Met established criteria
Durability & Lubricity & Fatigue	Met established criteria

Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the Chaperon Guiding Catheter System compared with the predicate device Penumbra Neuron Intracranial Access System (K070970).

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Use similar construction and material,
- Are packaged and sterilized using same processes.

In summary, the Chaperon Guiding Catheter System described in this submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2008

Microvention, Inc.
c/o Mark Job
Reviewer
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K082385
Trade/Device Name: Chaperon Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 11, 2008
Received: November 12, 2008

Dear Mr. Job:

This letter corrects our substantially equivalent letter of December 11, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Chaperon Guiding Catheter System

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052385