K113698

510(k) Summary

JAN 13 2012

Trade Name:	Scepter XC Occlusion Balloon Catheter
Generic Name:	Occlusion Balloon Catheter
Classification:	Class II, 21 CFR 870.4450
Submitted By:	MicroVention, Inc 1311 Valencia Avenue Tustin, California U.S.A.
Contact:	Naomi Gong
Date Prepared:	December 15, 2011

Predicate Device:

Number	Description	Clearance Date
K110741	MicroVention Scepter C Occlusion Balloon Catheter	September 29, 2011

Device Description:

The Scepter XC Occlusion Balloon Catheter is a dual coaxial lumen catheter with a non-detachable low inflation pressure compliant balloon attached to the distal end of the catheter. The catheter is designed to track over a steerable guidewire. Radiopaque marker bands are located at ends of the balloon and distal tip of the catheter to facilitate fluoroscopic visualization. The outer surface of the catheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the microcatheter hub is used for the attachment of accessories. The catheters are packaged sterile for single use only.

Indication For Use:

The Scepter XC Occlusion Balloon Catheter is intended for use in the peripheral and neurovasculature where temporary occlusion is desired. The balloon catheter provides temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The balloon catheter also offers balloon assisted embolization of intracranial aneurysms.

Verification and Test Summary:

Pre-clinical Testing	Result
Surface and physical attributes	Pass
Tensile strength	Pass
Leakage (liquid and air)	Pass
Static and dynamic burst pressure	Pass
Simulated use	Pass
Compatibility with devices	Pass
Kink resistance	Pass
Catheter flexural fatigue	Pass
Hydrophilic coating	Pass
Hub testing	Pass
Torque testing	Pass
Balloon testing – burst, compliance, deflation time, fatigue	Pass
Bicompatibility testing (ISO 10993-1)	Pass

Technological Comparison:

	Predicate Device	510(k) Subject Device
Lumen configuration	Dual coaxial lumen	Same
Inner Diameter	0.0165"	Same
Outer Diameter	2.6 – 2.8 F	Same
Balloon Diameter/Length	4 mm/ 10-20 mm	4 mm/10 mm
Material	Polyether block amide, polyolefin, stainless steel, PTFE, polyurethane elastomeric alloy, Pt/Ir, nylon, polyimide	Same
No. of Markers	3	Same
Coating	Hydrophilic coating	Same
Guidewire compatibility	0.014" or smaller wire	Same
Method of supply	Sterile and single use	Same

Summary of Substantial Equivalence:

The data presented in this submission demonstrates the technological similarity and equivalency of the Scepter XC Occlusion Balloon Catheter when compared with the predicate device, Scepter C Occlusion Balloon Catheter (K110741).

The devices,

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

In summary, the Scepter XC Occlusion Balloon Catheter described in this submission is in our opinion, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES —Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 13 2012

MicroVention, Inc.
c/o Naomi Gong
Regulatory Affairs Project Manager
1311 Valencia Avenue
Tustin, CA 92780

Re: K113698
Trade/Device Name: Scepter XC Occlusion Balloon Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: December 15, 2011
Received: December 16, 2011

Dear Ms. Gong:

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 application (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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. J. Hillebrenner

for 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): K113698

Device Name: Scepter XC Occlusion Balloon Catheter

Indications For Use:

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Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 Devices

510(k) Number K113698