K012348

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LUMEN BIOMEDICAL

Lumen Biomedical, Inc.

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Contact Person:	Maria Brittle Director Regulatory Affairs
Summary Date:	August 14, 2008
Product Trade Name:	FiberNet® Embolic Protection System
Common Name:	Embolic Protection Device
Classification Name:	Catheter, Percutaneous
Predicate(s):	K032884 FilterWire EZ™ Embolic Protection System K052659 SpideRX™ Embolic Protection System K072990 Guardwire System K071529 Xtract™ Aspiration Catheter
Intended Use:	The FiberNet® Embolic Protection System is indicated for use as a guidewire and emboli protection system to capture and remove embolic material (thrombus/debris) produced while performing percutaneous transluminal interventional procedures in carotid arteries in high surgical risk patients with reference vessel diameters of 3.5 to 7.0mm.
Device Description:	The system consists of a fiber filter on a 0.014" guidewire with attachable actuator tool (capture wire) and a 0.014" guidewire compatible aspiration catheter with attachable stopcock assembly (Xtract catheter, K071529). System accessories included in the package consist of two 30 ml syringes, a peel-away introducer, an actuation template, and a 40μm cell strainer cup.
Safety & Performance:	Non-Clinical: *In vitro* testing consisted of biocompatibility, sterilization, packaging, and product shelf life, and performance testing on the bench and in animals. Test results verified the device is adequate for its intended use and is equivalent to the predicate devices. Clinical: The EPIC Trial was a non-randomized multi-center study assessing device safety and performance when used with commercially available carotid stent systems in high surgical risk patients. Statistical analysis confirmed the FiberNet EPS rate met the performance goal based on ARCHeR3, demonstrating acceptable performance. Serious adverse events were similar in frequency and type to other studies.
Conclusion:	The FiberNet Embolic Protection System is substantially equivalent to the predicate embolic protection systems in technological characteristics and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Lumen Biomedical, Inc.
c/o Maria E. Brittle, PhD, RAC
Director, Regulatory Affairs
14505 21st Avenue North, Suite 212
Plymouth, MN 55447

Re: K082348
Trade/Device Name: FiberNet Embolic Protection System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: November 13, 2008
Received: November 14, 2008

Dear Dr. Brittle:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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 begin 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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/industry/support/index.html.

Sincerely yours,

Donna R. Vehmeyer

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): K082348

Device Name: FiberNet® Embolic Protection System

Indications for Use:

The FiberNet® Embolic Protection System is indicated for use as a guidewire and emboli protection system to capture and remove embolic material (thrombus/debris) produced while performing percutaneous transluminal interventional procedures in carotid arteries in high surgical risk patients with reference vessel diameters of 3.5 to 7.0 mm.

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)

Donna R. Vachner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082348