May 20, 2021

Lumen Biomedical, Inc.
Maria Brittle
14505 21st Ave. North
Suite 212
Plymouth, Minnesota 55447

Re: K080901
Trade/Device Name: LBI Embolectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW

Dear Maria Brittle:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 02, 2008. FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.05.20 10:12:08 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 02 2008

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

Re: K080901
LBI Embolectomy System (Models E5000, E6000, and E7000)
Regulation Number: 21 CFR 870.5150
Regulation Name: Catheter, Embolectomy
Regulatory Class: Class II
Product Code: DXE
Dated: September 16, 2008
Received: September 17, 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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device when used for embolic protection have not been established.

Furthermore, the indication for embolectomy use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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.

If you desire specific information about the application of other labeling requirements to your device (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" (21 CFR 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/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080901

Device Name: LBI Embolectomy System

Indications For Use:

The LBI Embolectomy System is indicated for use in removal of fresh, soft emboli and thrombi from vessels in the peripheral vasculature.

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 K080901

LUMEN BIOMEDICAL

OCT 02 2008

K080901

Lumen Biomedical, Inc.

14505 21st Avenue North, Suite 212
Plymouth, MN 55447
(763) 577-9600 Business
(763) 577-1044 Fax

Contact Person:	Maria Brittle Director Regulatory Affairs
Summary Date:	June 27, 2008
Product Trade Name:	LBI Embolectomy System
Common Name:	Catheter, embolectomy
Classification Name:	Catheter, embolectomy
Predicate(s):	K071529 Xtract Catheter K892410 Fogarty Thru-Lumen Embolectomy catheter K002627 ClearWay PTFE Balloon Catheter K062275, K050130 Rinsperation System K040010 F.A.S.T. System K991093 MSD Embolectomy basket K990639 Hi-Torque Cross-It 300XT guidewire K994358 ATW guidewire
Intended Use:	The LBI Embolectomy System is for use in removal of fresh, soft emboli and thrombi from vessels in the peripheral vasculature.
Device Description:	The system consists of a 0.014" guidewire compatible aspiration catheter with attachable stopcock assembly (Xtract catheter, K071529) and a fiber element on a 0.014" guide wire with attachable actuator tool. 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:	Equivalency was demonstrated through comparison to predicate devices, biocompatibility, *in vitro* and animal testing.
Conclusion:	This product is substantially equivalent[1] and acceptable for the intended use.

[1] This document uses the term "substantial equivalent" as intended in 21 CFR 807.87 and not as defined in Title 36 of the U.S. Code.