September 15, 2021

Lumen Biomedical, Inc.
Amy Peterson
Consultant
2605 Fernbrook Lane
Suite A
Plymouth, Minnesota 55447

Re: K053372
Trade/Device Name: LBI Catheter System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Amy Peterson:

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 June 30, 2006. Specifically, 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: 2021.09.15 09:13:41 -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

Lumen Biomedical, Inc.
c/o Ms. Amy Peterson
2605 Fernbrook Lane, Suite A
Plymouth, MN 55447

JUN 3 0 2006

Re: K053372
Trade/Device Name: LBI Catheter System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: June 26, 2006
Received: June 27, 2006

Dear Ms. Peterson:

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 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/industry/support/index.html.

Sincerely yours,

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): K053372

Device Name: LBI Catheter System

Indications for Use: The LBI Catheter System is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system.

Prescription Use ___X___ AND/OR Over-The- Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 K053372

JUN 30 2006

510(k) Summary – K053372
June 29, 2006

Trade Names:	Xtract™ Catheter System
Manufacturer:	Lumen Biomedical, Inc., 14505 21st Ave N., Suite 212, Plymouth, MN 55447
Official Contact:	Amy Peterson, Vice President RA & QA Telephone: (763) 746-9550 Fax: (763) 577-1044
Device Generic Name:	• Catheter, embolectomy
Classification:	• Catheter, embolectomy, 21 CFR §870.5150 • Class II, Product Code - DXE • Panel – Cardiovascular
Predicate Devices:	• Pronto Extraction Catheter, K032763, K042937, K051193*, K052232 • Export Aspiration Catheter, K040869, K050139
Device Description:	The Lumen Biomedical Inc. (LBI) Xtract™ Catheter System is a single-use, 0.014" guidewire compatible, temporary intravascular extraction and aspiration catheter system. It has a distal radiopaque tip marker, a varying stiffness shaft, a rapid exchange port, and a proximal luer-lock hub. The system consists of one (1) Catheter, one (1) Extension Tube with Stopcock, two (2) 30cc Aspiration Syringes, and one (1) 40μm Strainer.
Indication for Use:	The Xtract™ Catheter System is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system.
Safety & Performance:	The results of the *in vitro* bench, biocompatibility, and animal tests demonstrate the Xtract™ Catheter System for aspiration/extraction is substantially equivalent to the predicate devices. Applicable standards were applied: per ISO 10555-1, 10993-1, 11135, ASTM D 4169-05 (DC13), F 1980-02, F 2096-04 and F 88-05 to demonstrate substantial equivalence[1]. No new safety or effectiveness questions were identified.
Conclusion:	This product is substantially equivalent[1] and considered 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.