DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 16, 2016

Biocompatibles UK Limited
Dr. Simon Leppard
Director of Regulatory Affairs
Chapman House, Farnham Business Park, Weydon Lane
Farnham, Surrey GU9 8QL GB
United Kingdom

Re: K162373
Trade/Device Name: LC Bead LUMI
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: November 16, 2016
Received: November 17, 2016

Dear Simon Leppard:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Brian D. Pullin -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162373

Device Name
LC Bead LUMI

Indications for Use *(Describe)*
LC Bead LUMI is intended to be used for the embolization of hypervascular tumors and arteriovenous malformations (AVMs).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(k) Summary

LC Bead LUMI™ (BTG 13-002)

(per 21 CFR 807.92)

5.1 Submitter

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Date Prepared: December 14, 2016

5.2 Device

Name of Device: LC Bead LUMI™ Radiopaque Embolic Bead
Common or Usual Name: Vascular Embolization Device
Classification Name: Vascular Embolization Device (21 CFR 870.3300)
Regulatory Class: II
Product Code: KRD

5.3 Predicate Devices

Primary Predicate Device:
LC Bead LUMI™ microspheres
Manufacturer: Biocompatibles UK Ltd.
K152157 LC Bead LUMI
Product code: KRD
CFR section 870.3300
This predicate has not been subject to a design-related recall.

Embozene® Microspheres
CeloNova Biosciences, Inc.
K132675

Product Code: KRD
CFR Section: 870.3300

5.4 Device Description

LC Bead LUMI™ is an imageable spherical embolic product that can be visualised by X-ray based imaging (e.g. fluoroscopy and CT). The beads are non-resorbable microspheres with calibrated size ranges. LC Bead LUMI™ are intended to be used for the embolization of hypervascular tumours and arteriovenous malformations (AVM).

LC Bead LUMI™ are supplied in a saline buffer solution within a sealed glass vial. A vial access device is also provided within the secondary packaging. LC Bead LUMI™ is provided sterile (moist heat sterilization).

LC Bead LUMI™ consist of a macromer derived from a sulphonate modified polyvinyl alcohol (PVA) macromer which contains a radiopaque moiety that is covalently bound within the hydrogel structure. The incorporation of this radiopaque moiety into the co-polymer imparts X-ray imageability by rendering the microspheres radiopaque.

LC Bead LUMI™ has been designed as a radiopaque version of LC Bead™. Currently embolization with LC Bead™ lacks post-procedural imaging feedback on exact bead location. The embolization process with LC Bead™ is monitored by detecting changes in antegrade flow of soluble iodinated contrast in which the beads are diluted. The embolization is continued until a desired embolization endpoint is reached. This process is completed without specific feedback on the bead location. In order to address this limitation, the manufacturer has developed an imageable spherical embolic bead that can be visualized by X-ray based imaging.

At the time of use, LC Bead LUMI™ is mixed with non-ionic contrast agent in order to monitor the delivery of the product during the embolization procedure. LC Bead LUMI™ is delivered via typical microcatheters to physically block the target vessel. Once the product has been delivered the iodine moiety allows for visualization of the microspheres. LC Bead LUMI™ is a single use, tissue contacting, implantable device available only for prescription use.

LC Bead LUMI™ is available in the following four size ranges:

Stated Size Range
40-90 µm
70-150 µm
100-300 µm
300-500 µm

Table 1 Size ranges of LC Bead LUMI™

One associated accessory is provided with LC Bead LUMI™:

- 20 mm ViaLok Vented Vial Access Device – aids bead removal from vial

5.5 Indications for Use

LC Bead LUMI™ are intended to be used for the embolization of hypervascular tumors and arteriovenous malformations (AVMs).

5.6 Comparison of Technological Characteristics with the Predicate Devices

The intended use of LC Bead LUMI™ remains unchanged compared to the primary predicate device LC Bead LUMI™ (cleared by FDA in December 2015, K152157). The subject device (LC Bead LUMI™) and the primary predicate LC Bead LUMI™ have the same design, specifications, scientific technology, and packaging. The key difference to the primary predicate device is the addition of a smaller bead size (40 – 90µm) which is in the same range as the commercially available second predicate device Embozene® Microspheres, CeloNova (see Table 2).

LC Bead LUMI™ (Subject device) (21CFR870.3300)	**LC Bead LUMI™ (Predicate)*** (21CFR870.3300)	**Embozene® Microspheres CeloNova (Predicate)** (21CFR870.3300)
40-90 µm	-	40 ± 10µm 75 ± 15µm 100 ± 25µm
70-150µm	70-150µm	100 ± 25µm
100-300µm	100-300µm	250 ± 50µm
300-500µm	300-500µm	400 ± 50µm 530 ± 50µm (larger sizes available)

Table 2 Size ranges of LC Bead LUMI™ and predicates; *cleared (K152157)

The substantial equivalence claim of the subject device LC Bead LUMI™ (incl. the smallest size range 40 – 90µm) with Biocompatibles UK Ltd own pre-existing marketed device LC Bead LUMI™ and the CeloNova BioSciences Embozene Microspheres is based on the equivalence with the following elements:

- Device material
- Intended use
- Size specification
- Target population
- Mode of action

- Application location
- Route of application
- Biological characteristics / bench and animal performance

The key difference of the subject device LC Bead LUMI™ to the primary predicate device LC Bead LUMI™ (K152157) is the addition of the bead size 40 – 90µm.

5.7 Performance Data

Bench testing data, verification and validation studies and in-vivo safety and performance studies involving LC Bead LUMI™ show that the subject device has equivalent safety and performance to the predicate devices.

The performance data were provided in support of the substantial equivalence determination. Both biocompatibility and animal testing were conducted in accordance with “FDA Guidance - Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices, December 29, 2004”.

5.8 Conclusions

The subject device of this 510k submission, LC Bead LUMI™, is substantially equivalent to the predicate devices LC Bead LUMI™ (K152157) and Embozene® Microspheres, (K132675) in terms of indication for use, target population, mode of action, route and location of administration, and is identical to the primary predicate in its product characteristics of chemistry and device material. The key difference between the primary predicate device and the subject device is the addition of the 40 – 90µm bead size. The subject device is substantially equivalent to the predicate Embozene® CeloNova with respect to the smallest bead size (40 – 90µm). In vitro bench testing and non-clinical testing in animals support that the subject device has equivalent safety and performance to the predicate devices.