



Food and Drug Administration
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December 11, 2015

Biocompatibles UK Ltd.
% Robert Lally
Senior Vice President Regulatory Affairs
BTG International Inc.
Five Tower Bridge, Suite 800
300 Barr Harbor Drive
West Conshohocken, Pennsylvania 19428

Re: K152157
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: October 29, 2015
Received: November 4, 2015

Dear Robert Lally:

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 yours,

Kenneth J. Cavanaugh -S

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)

K152157

Device Name

LC Bead LUMI

Indications for Use (Describe)

LC Bead LUMI are 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.

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5 510(k) Summary

K152157

LC Bead LUMI™ (BTG 13-002)

(per 21 CFR 807.92)

5.1 Submitter

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Date Prepared: April 17, 2015

5.2 Device

Name of Device: LC Bead LUMI™
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 Device

LC Bead™ Microspheres
K083091 LC Bead Microspheres / Bead Block Compressible Microspheres
Manufacturer: Biocompatibles UK Ltd.
CFR 870.3300
Product code: KRD



This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

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 tumors 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 the 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 visualised 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 three size ranges:

Stated Size Range
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™:

- Vented vial access device, 20mm – aids bead removal from vial

5.5 Indications for Use

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

The indication for use statement for LC Bead LUMI™ is identical to the predicate device LC Bead™.

5.6 Comparison of Technological Characteristics with the Predicate Device

The intended use of LC Bead LUMI™ and the predicate device are the same and unchanged. Biocompatibles UK Ltd intends to market LC Bead LUMI™ in only three size ranges (see Table 2) which fall within the same size ranges commercially available for the predicate device. For each size range the size specification to the predicate device is unchanged.

LC Bead (Predicate) (21CFR870.3300 and 21CFR882.5950)	LC Bead LUMI™ (21CFR870.3300)
70-150µm	70-150µm
100-300µm	100-300µm

LC Bead (Predicate) (21CFR870.3300 and 21CFR882.5950)	LC Bead LUMI™ (21CFR870.3300)
300-500µm	300-500µm
500-700µm	-
700-900µm	-
900-1200µm	-

Table 2 Size ranges of LC Bead LUMI™ and LC Bead™

The substantial equivalence claim of LC Bead LUMI™ embolization device with Biocompatibles UK Ltd own pre-existing marketed device LC Bead™ 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

As per the predicate device, LC Bead LUMI™ consist of a macromer derived from a sulphonate modified polyvinyl alcohol (PVA) macromer. Additionally LC Bead LUMI™ 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 device radiopaque. The inclusion of this radiopaque moiety and related process modifications (such as coupling of the radiopaque moiety as well as omission of a blue dye used for the predicate) is the key differentiator between LC Bead LUMI™ and LC Bead™. In addition to the inclusion of the radiopaque moiety there are some additional changes to the endotoxin and solvent limits.



5.7 Performance Data

Bench testing data, verification and validation studies, in vitro and in-vivo biocompatibility 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 device.

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 manufacturer has provided a detailed comparison of the product LC Bead LUMI™ to demonstrate substantial equivalence of this product to the predicate LC Bead™ in terms of indication for use, target population, mode of action, route and location of administration as well as product characteristics such as chemistry and bead size. Given the key difference between the predicate and the subject device is the ability to visualize LC Bead LUMI™, by imaging techniques, Biocompatibles UK Ltd has generated a set of in vitro and in-vivo biocompatibility data as well as further bench and non-clinical data to support that the subject device has equivalent safety and performance to the predicate device. The results of the LC Bead LUMI™ non-clinical data support the conclusion that the addition of the radiopaque moiety does not raise different questions of safety of the subject device. Changes in the manufacturing process based on the introduction of the radiopaque moiety do not raise new questions of safety and effectiveness of the subject device. In conclusion, the bench testing data, verification and validation data show that performance is substantially equivalent to the predicate device.