Biopharm (UK) Ltd.
Attention: Bethany Sawyer
2 Bryngwili Road
Hendy, Carmarthenshire
SA4 OXT
Wales, UK

June 30, 2025

Re: BK 251217 (Formerly K132958)
Trade/Device Name: European Medicinal Leeches - Hirudo verbena
Regulation Number: Pre-Amendment
Regulation Name: Pre-Amendment
Regulatory Class: Unclassified
Product Code: NRN

Dear Bethany Sawyer:

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 February 19, 2014. Specifically, FDA is updating this SE Letter because FDA has assigned your submission a new submission tracking number.

Please update the registration and listing of the device within the FURLS Device Registration and Listing Module according to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm.

For more information, please refer to the Federal Register Notice *Transfer of Regulatory Responsibility From the Center for Devices and Radiological Health to the Center for Biologics Evaluation and Research; Medical Maggots and Medicinal Leeches* (89 FR 106521, available at https://www.federalregister.gov/documents/2024/12/30/2024-31266/transfer-of-regulatory-responsibility-from-the-center-for-devices-and-radiological-health-to-the).

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact the Regulatory Project Manager, Hosna Keyvan by email at hosna.keyvan@fda.hhs.gov.

Sincerely,

Steven S. Oh, PhD
Deputy Director
Office of Cellular Therapy and Human Tissue
Office of Therapeutic Products
Center for Biologics Evaluation and Research

Enclosure: SE Letter K132958

K132958

FEB 19 2014

BIOPHARM (UK) LTD.

(Suppliers of leeches since 1812)

BIOPHARM (UK) LTD
Bryngelen Manor
2 Bryngwili Road
Hendy, Carms
SA4 0XT
Tel : (01792) 885595
FAX : (01792) 882440
sales@biopharm-leeches.com
www.biopharm-leeches.com

Amended 510(k) Summary

Date prepared: December 18, 2013

1. Sponsor

Biopharm (UK) Ltd.
2 Bryngwili Road
Hendy
Carmarthenshire
SA4 0XT
Wales
UK

Tel: 011 44 1792 885595 Fax: 011 44 1792 882440
Contact Name: Bethany Sawyer, Manager
E-mail: bethanysawyer@biopharm-leeches.com

2. System Identification

A. Proprietary Name
Medicinal Leeches

B. Common or Usual Product Name
European Medicinal Leeches – *Hirudo verbana*

C. Product Classification
Preamendment Device – Unclassified

3. Description of the Device

The device is a European Medicinal Leech (*Hirudo verbana).* It is a greenish segmented worm of the Annelida worm classification. The animal is a bloodsucking animal living in freshwater.

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4. How the Device Functions- Including Scientific Concepts Which Form the Basis of the Device

The saliva of the leech contains an anticoagulant (Hirudin) which is responsible for the prolonged bleeding which occurs after the leech has detached. This prolonged bleeding is used in instances where blood has become congested.

5. Intended Use of the Device

Leeches may be used in instances where skin flaps, skin grafts, or other tissues are suffering from impaired venous circulation. Leeches can be used to alleviate the problem of venous congestion by creating prolonged localized bleeding.

6. Conditions the Device Will Be Used to Treat

Leeches may be used in instances where skin flaps, skin grafts, or other tissues are suffering from impaired venous circulation. Leeches can be used to alleviate the problem of venous congestion by creating prolonged localized bleeding.

7. Predicate Device

510(k) number: K040187 – Trade name: Medicinal Leeches

8. Summary of the Characteristics of Our Device Compared to Its Predicate

Our device and its predicate share the same characteristics, they are both European Medicinal Leeches which are segmented worms of Annelida worm classification. The only difference is that our device is scientifically categorized as the species *Hirudo verbana* (Southern European Medicinal Leeches) and the predicate is classified as *Hirudo medicinalis* (Northern European Medicinal Leeches).
On 02/24/2010 at the CITES Conference of Parties (CoP15) it was agreed that the European Medicinal Leech would be divided into two categories (Northern - *Hirudo Medicinalis,* and the Southern - *Hirudo verbana)* based on their geographical distribution. Prior to this all European Medicinal Leeches were classified as *Hirudo medicinalis*.
There are no known differences in the activity spectrums of the two European variants. The two medicinal leech species are used as exact equivalents for use in overcoming problems with venous congestion.

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9. Packaging Material Used in Leech Transport

Leeches are shipped in a tied cloth bag, and as with Biopharm (UK) Ltd shipments a sterile polyacrylamide gel is used to keep the leeches moist during transit. The cloth bags are then housed in paper cartons with lids. Polystyrene boxes are used as they maintain a lower internal box temperature. Other polystyrene chips are also used to further insulate the shipment and prevent the cartons moving around too much. Ice packs are sometimes used, depending on the weather, to insure that the leeches do not get over heated.

10. Methods by Which "Used" Leeches are Disposed of as Biohazard Material

As in any situation where exposure to human fluids is possible, wear personal protective equipment as mandated by local regulations. Gloves should be worn at all times when handling leeches that have been used on a patient. Any areas touched by the leech should be treated in a manner similar to contamination by human body fluids. Leeches that have been used on a patient can be disposed of by immersing them in a solution of 70% (or higher) alcohol. Leave them in the alcohol for at least 5 minutes. Once the leeches are fully euthanized package and dispose of them according to the regulations set out by your County and State for liquid biohazard waste.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 19, 2014

Biopharm U.K. Ltd.
Ms. Bethany Sawyer
Bryngelen Manor
2 Bryngwili Road
Hendy, Pontarddulais
Swansea, United Kingdom SA4 0XT

Re: K132958
Trade/Device Name: Medicinal Leech
Regulatory Class: Unclassified
Product Code: NRN
Dated: January 15, 2014
Received: January 22, 2014

Dear Ms. Sawyer:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132958

Device Name: Medicinal Leech

Indications For Use: Leeches may be used in instances where skin flaps, skin grafts, or other tissues are suffering from impaired venous circulation. Leeches may be used to alleviate the problem of venous congestion by creating prolonged localized bleeding.

Prescription Use___X__AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Jiyoung Dang -S