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

August 7, 2015

Carolina Biological Supply Company
Mr. Keith E. Barker
Manager, Product Safety and Compliance
2700 York Road
Burlington, North Carolina 27215

Re: K140907
Trade/Device Name: Medicinal Leech
Regulatory Class: Unclassified
Product Code: NRN
Dated: July 7, 2015
Received: July 8, 2015

Dear Mr. Barker:

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" (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 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K140907

Device Name
Medicinal Leech

Indications for Use *(Describe)*
Medicinal leeches may be used in instances where skin flaps, skin grafts, surgical reattachments, or other tissues are adversely affected by impaired venous blood flow. Leeches may be used to alleviate the problem of venous congestion and delayed healing by creating prolonged localized bleeding.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

CAROLINA®
World-Class Support for Science & Math

510(k) SUMMARY

August 6, 2015

Owner

Carolina Biological Supply Company
2700 York Road
Burlington NC 27215 USA

Telephone: 336-584-0381
Fax: 336-538-6285
Contact: Keith Barker, Manager, Product Safety and Compliance
E-mail: keith.barker@carolina.com

Device

Trade Name: Medicinal Leech
Common and Scientific Names: European Medicinal Leech, *Hirudo verbana*
Alternatively: European Medicinal Leech, *Hirudo medicinalis*
Product Classification: Unclassified

Equivalent Legally Marketed Product

510(K)	MANUFACTURER	PRODUCT	DATE
K040187	Ricarimpex SAS	Medicinal Leeches *(Hirudo Medicinalis)*	06-21-04
K132958	Biopharm (UK) Ltd	European Medicinal Leeches *(Hirudo Verbena)*	02-19-14

Product Description

The Medicinal Leech is a laboratory-raised bloodsucking annelid (segmented worm) that inhabits fresh water. The leech has a cylindrical body, is slightly flattened, and has around 32 segments. It has a disc-shaped sucker at the head end and a tail sucker at the caudal end.

Product Function

When the leech attaches to the patient's skin to obtain a blood meal, it typically results in prolonged localized bleeding which can help alleviate the problem of venous congestion.

Indications for Use

Medicinal leeches may be used in instances where skin flaps, skin grafts, surgical reattachments, or other tissues are adversely affected by impaired venous blood flow. Leeches may be used to alleviate the problem of venous congestion and delayed healing by creating prolonged localized bleeding.

CAROLINA®
World-Class Support for Science & Math

Summary of the Characteristics of Device Compared to Predicates

Carolina Biological Supply Company (Carolina) will normally obtain and offer medicinal leeches that are identical to those approved under K132958, with scientific name Hirudo verbana. If necessary, Carolina may obtain (from a registered source with an approved and registered device) and offer medicinal leeches with scientific name Hirudo medicinalis, as are approved under K040187. Carolina's product is identical to predicate devices.

Therapeutic Benefits

The major therapeutic benefits of leech application are not derived from the average 5 mL of blood removed during biting (although this may provide immediate, dramatic relief at first), but from the successive release of up to 150 mL of blood for 10 or more hours following the bite.

Facilities and Handling

Leeches are held in a dedicated, sanitized refrigerated cold room in containers that were initially sanitized by the leech supplier. When reapportioning the leeches is necessary, several controls are in place to avoid contamination. These controls are periodic well water testing for chemical and biological contaminants, careful sanitization of new containers and all leech-handling utensils, limited access to the cold room, use of gloves, and periodic sanitation procedures of all surfaces with bleach.

Packaging and Transport

Repackaging is done just prior to shipment. Leeches are packed into cloth bags with a sterile polyacrylamide gel. The bags are tied. The cloth bags are placed in paper containers with lids, and the paper container is placed in a foam cooler inside a corrugated carton. Ice packs, when needed, are placed in the foam cooler, along with sufficient packing foam to secure the package contents. Foam package is closed, instruction manual is placed on top, and the corrugated carton is sealed.

Leech Storage

Medicinal Leeches should be stored in a refrigerator or another cool, dark place for ease of maintenance until they are needed. Leeches will survive for weeks, sometimes months, at temperatures in the range of 5-10°C (as their metabolic activity levels will be low).

Leech Disposal

Leeches that have been used on a patient can be disposed of by immersing them in a solution of 70% (or higher) isopropyl alcohol. Leave them in the alcohol for at least 5 minutes and then dispose of them in the same manner as any other potentially infectious biological waste.

Carolina Biological Supply Company
2700 York Road • Burlington NC 27215-3398 • Phone 336.584.0381 • Fax 800.222.7112 • www.carolina.com