Ricarimpex SAS June 18, 2025

Attention: Brigitte Latrille
245 Avenue de Saint Medard
33320 Eysines
France

Re: BK251211/0 (Formerly K040187)
Trade/Device Name: Medicinal Leeches
Regulation Number: Pre-Amendment
Regulation Name: Pre-Amendment
Regulatory Class: Unclassified
Product Code: NRN

Dear Brigitte Latrille:

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 21, 2024. 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, Mona Badawy by email at Mona.Badawy@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 K040187

JUN 2 1 2004

K040187

510(k) Summary

Date Prepared: January 15, 2004

Sponsor

A Sponsor Name

Ricarimpex SAS
245 Avenue de Saint Médard
33320 Eysines
France
Tel: 011 33 5 56 57 84 12 Fax: 011 33 5 56 57 84 14

Contact Name: Ms. Brigitte Latrille, President
E-mail: ricarimpex@leeches-medicinalis.com

2. System Identification

A. Proprietary Name

Medicinal Leeches

B. Common or Usual Product Name

Hirudo Medicinalis

C. Product Classification

Preamendment Device - Unclassified

Predicate Device

None - Medicinal Leeches are a preamendment device which has yet to be classified

Medicinal Leeches Device / Substantial Equivalence Information

The application of leeches as an alternative medicinal treatment as opposed to "previous, predicate devices/methods", such as blood letting and amputation is one of histories oldest treatments whose use can be documented as far back as ancient Egypt and was standard medical practice until the mid 1800's.

Over the past decades surgeons have once again begun to use medicinal leeches as a means to restore venous blood circulation following cosmetic and reconstructive surgery.

Since the leeches bite produces a small amount of bleeding which mimics venous circulation in areas of compromised tissue it is of value in healing following plastic and reconstructive surgery. A leech bite produces anticoagulant and vasodilator substances which allow continued bleeding to improve venous circulation even after the animal has been removed from the patient.

Medicinal leeches, a blood sucking aquatic animal living in fresh water and subject to regulation by the U.S. Fish and Wildlife Service, are a preamendment, unclassified device which, by nature of their historical use and documented value in various post surgical situations,

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 1 2004

Ms. Brigitte Latrille
President
Ricarimpex SAS
245 Avenue de Saint Médard
33320 Eysines
France

Re: K040187
Trade/Device Name: Medicinal Leeches
Regulatory Class: Unclassified
Product Code: NRN
Dated: May 11, 2004
Received: May 17, 2004

Dear Ms. Latrille:

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

K040187

510(k) Number (if known):

Device Name: Medicinal Leeches (Hirudo Medicinalis)

Indications For Use: An adjunct to the healing of graft tissue when problems of venous congestion may delay healing, or to overcome problems 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 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K040187