Les Laboratoires Brothier S.A.
% Sheila Hemeon-Heyer
President and Founder
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, Massachusetts 01002

April 21, 2023

Re: K183622
Trade/Device Name: NasalCEASE and BleedCEASE
Regulatory Class: Unclassified
Product Code: QSY, LYA

Dear Sheila Hemeon-Heyer:

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 December 2, 2019. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product codes QSY and LYA.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

December 2, 2019

Les Laboratoires Brothier S.A.
% Sheila Hemeon-Heyer
President and Founder
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, Massachusetts 01002

Re: K183622
Trade/Device Name: NasalCEASE and BleedCEASE
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 29, 2019
Received: July 30, 2019

Dear Sheila Hemeon-Heyer:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kimberly Ferlin -S

Kimberly M. Ferlin, Ph.D.
Assistant Director (acting)
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183622

Device Name

BleedCEASE® and NasalCEASE®

Indications for Use *(Describe)*

OTC: For the local management of bleeding wounds such as minor cuts, minor lacerations, minor abrasions, and minor nosebleeds.

Prescription: For nasal epistaxis and the local management of topical wounds, including both non-infected and infected:

- Small bleeding surface wounds
- Small post-surgical incisions
- Abrasions and lacerations

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."

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

A. 510(k) Submitter:

Heyer Regulatory Solutions LLC
P.O. Box 2151
Amherst, MA 01004-2151
Contact: Sheila Hemeon-Heyer
Sheila@heyer-regulatory.com

B. 510(k) Applicant / Manufacturer / Contact:

Les Laboratoires Brothier S.A.
41 Rue de Neuilly
92735 Nanterre, France
Contact: Erna Milos
Tel: +33 0 1 56 38 30 00
Fax: +33 0 1 41 20 93 70
milos@brothier.com

C. Date Prepared: December 2, 2019

D. Device Name and Classification Information:

Trade Name:	BleedCEASE® and NasalCEASE®
Classification Name:	Dressing, wound, drug
Regulatory Class:	Unclassified
Product Code:	FRO

E. Predicate Device: For OTC use: NasalCEASE® (K102742)
For prescription use: Algosteril (K922540), and ENTaxis (K984069)

F. Device Description:

BleedCEASE® and NasalCEASE® are the same product with the same indications for use but branded under two different names. The remainder of this summary will refer to the product as BleedCEASE.

BleedCEASE® is made of calcium alginate, an all-natural biopolymer originating from seaweed. When in contact with the wound, BleedCEASE® absorbs blood and releases calcium, becoming a soft gel that conforms to the wound. BleedCEASE stops bleeding

without sticking to the wound, reducing the likelihood of pain or rebleeds that may be associated with wound dressing removal.

BleedCEASE® is provided as a sterile, non-woven packing (2cm x 4cm), each packaged in an individual pouch. The product is sold in boxes of 5, 25 and 100 pouches.

G. Indications for Use:

OTC: For the local management of bleeding wounds such as minor cuts, minor lacerations, minor abrasions, and minor nosebleeds.

Prescription: For nasal epistaxis and the local management of topical wounds, including both non-infected and infected:

- Small bleeding surface wounds
- Small post-surgical incisions
- Abrasions and lacerations

H. Comparison to Predicate Device

BleedCEASE® and NasalCEASE® are the same product, and are manufactured, packaged, and sterilized using the same processes as the two predicate devices, both of which are non-woven calcium alginate wound dressings manufactured by the 510(k) applicant, Les Laboratoires Brothier. The purpose of this 510(k) is for labelling changes only. The labelling changes include:

- Modifications to the OTC instructions for use, including:
  - Removal of the statement that the product is not approved for nosebleeds by children 12 and under
  - Addition of a caution that use for nosebleeds in children 12 and under should be with adult supervision
  - Removal of warning regarding toxic shock syndrome (TSS) as there is no evidence of TSS associated with many years of product use
- Addition of labeling for prescription use to enable the product to be prescribed by clinicians. The proposed product is substantially equivalent to two predicate calcium alginate wound dressings manufactured by Les Laboratoires Brothier: Algosteril (K922540), which was cleared for prescription use in the local management of partial and full thickness wounds and other wounds such as abrasions and lacerations, and ENTaxis (K984069), cleared for nasal epistaxis and post-surgical nasal packing. BleedCEASE is made of the same material and manufacturing processes as these predicate devices. The only difference is that BleedCEASE is available as a smaller swab (2 cm x 4 cm), which limits the application of

BleedCEASE to smaller wounds. However, BleedCEASE has the same mechanism of action as the predicate calcium alginate hemostatic wound dressings.

I. Safety and Performance Data:

There have been no changes to the product materials, manufacturing, packaging, or sterilization processes. No safety or performance testing is required to support this 510(k) application, which is for labeling changes only.

I. Conclusion

The information provided in this 510(k) Premarket Notification supports the proposed changes to the product labelling and a conclusion of substantial equivalence.