



Baxter Healthcare Corporation
c/o Jesse K. Seidman, M.S.
Associate Director, Global Regulatory Affairs
1620 Waukegan Road
McGaw Park, Illinois 60085

July 28, 2023

Re: K103245
Trade/Device Name: CELSTAT Topical Hemostatic Dressing
Regulatory Class: Unclassified
Product Code: QSY

Dear Jesse K. Seidman, M.S.:

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 March 23, 2011. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSY.

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



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Baxter Healthcare Corporation
% Mr. Jesse K. Seidman, M.S.
Associate Director, Global Regulatory Affairs
1620 Waukegan Road
McGaw Park, Illinois 60085

MAR 23 2011

Re: K103245

Trade/Device Name: CELSTAT Topical Hemostatic Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 13, 2011
Received: January 18, 2011

Dear Mr. Seidman:

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

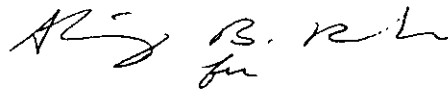
Page 2 - Mr. Jesse K. Seidman, M.S.

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K103245

Device Name: CELSTAT Topical Hemostatic Dressing

Indication for Use:

CELSTAT is indicated for topical external use in the management of topical wounds and to temporarily control moderate to severe bleeding from the skin.

Prescription Use: AND/OR Over-the-Counter Use:
21 CFR 801 Subpart D 21 CFR 801 Subpart C

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krane for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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510(k) Number K103245

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Traditional 510(k) Premarket Notification
CELSTAT Topical Hemostatic Dressing

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Section 5 510(k) Summary

5. 510(K) SUMMARY

DATE: October 29, 2010

CONTACT PERSON: Jesse Seidman
Baxter Healthcare Corporation
Associate Director, Global Regulatory Affairs
1620 Waukegan Road, MPGR-AL
McGaw Park, IL 60085
Telephone: 847-948-3031
Fax: 847-785-5116
Email: jesse_seidman@baxter.com

DEVICE NAME: **Trade Name:** CELSTAT
Common Name: Topical Hemostatic Dressing
Classification: Wound Dressing
Class: Unclassified
Product Code: FRO

PREDICATE DEVICE:

Predicate 510(k)	Device Name	Indication	Clearance Date	Company
K072681	BloodSTOP and BloodSTOP iX Hemostatic Gauze	CELSTAT is indicated for topical external use in the management of topical wounds and to temporarily control moderate to severe bleeding from the skin.	November 2, 2007	LifeScience Plus, Inc., P.O. Box 60783, Palo Alto, CA 94306

DEVICE

DESCRIPTION:

CELSTAT is a topical hemostatic dressing made of oxidized cellulose. It is a sterile, biocompatible, biodegradable hemostatic material designed to temporarily control moderate to severe bleeding from the skin.

**STATEMENT OF
INTENDED USE:**

CELSTAT is indicated for topical external use in the management of topical wounds and to temporarily control moderate to severe bleeding from the skin.

**TECHNOLOGICAL
CHARACTERISTICS:**

The CELSTAT device is substantially equivalent to the predicate device with regard to technological characteristics, performance, and intended use.

**ASSESSMENT OF
NONCLINICAL DATA:**

Baxter Healthcare Corporation conducts risk analysis according to the requirements of ISO 14971:2007 Medical Devices-Application of Risk Management to Medical Devices.

The device continues to meet the same material testing standards and sterilization process standards as the predicate device. Device performance has been demonstrated according to a porcine liver square model animal study and biocompatibility testing.

CONCLUSIONS:

The CELSTAT device is substantially equivalent to the predicate device. Testing against established standards and guidelines for its intended use demonstrate that the proposed device is as safe and effective as the predicate device.