February 2, 2023

BC3 Technologies Inc
Wayne Grube
CEO
3701-A Southwestern Blvd
Baltimore, Maryland 21229

Re: K210751
Trade/Device Name: S.E.A.L. Hemostatic Wound Spray
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 20, 2022
Received: December 20, 2022

Dear Wayne Grube:

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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210751

Device Name
S.E.A.L. Hemostatic Wound Spray

Indications for Use *(Describe)*

Prescription Use:

• S.E.A.L. Hemostatic Wound Spray is intended to be used to achieve hemostasis in emergency situations for the temporary control of severe topical bleeding.

OTC:

• S.E.A.L. Hemostatic Wound Spray is indicated for the local management of minor bleeding such as minor lacerations, minor cuts and minor abrasions.

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.

I. SUBMITTER

Submitter of 510(k):

BC3 TECHNOLOGIES INC
3701 Southwestern Blvd
Baltimore, MD 21229
m: +1.443.204.7260 - p: +1.410.342.6100

Contact Person: Wayne L. Grube Jr.
waynegrube@bc3tech.com

II. DEVICE

Name of Device: S.E.A.L. Hemostatic Wound Spray ("S.E.A.L.")

Common or Usual Name: Hemostatic wound dressing

Classification Name: Unclassified – Device, Dressing

Regulatory Class: NA

Product Code: FRO

III. PREDICATE DEVICE

Primary Predicate:
CELOX Topical Hemostatic Granules (K061079)
Manufactured by MedTrade Products

Supporting Predicate:
Seal-On™ Hemostatic Powder Spray (K010933)

The predicate devices have not been subject to a design-related recall.

IV. DESCRIPTION

S.E.A.L. Hemostatic Wound Spray is composed of chitosan dry powder in spray form that provides a physical barrier or seal to stop the flow of blood. When

sprayed on a wound and upon contact with blood or exudate, in combination with manual pressure to the wound, S.E.A.L. quickly forms a strong seal that completely covers the wound. S.E.A.L. is presented for both Prescription and over-the-counter (OTC) use.

S.E.A.L. is available in three different sizes:

Model	Volume
Small	1.33 oz
Medium	1.66 oz
Large	3.33 oz

V. INDICATIONS FOR USE

Prescription Use:

- S.E.A.L. Hemostatic Wound Spray is intended to be used to achieve hemostasis in emergency situations for the temporary control of severe topical bleeding.

OTC:

- S.E.A.L. Hemostatic Wound Spray is indicated for the local management of minor bleeding such as minor lacerations, minor cuts and minor abrasions.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

- MedTrade Products CELOX Topical Hemostatic Granules (K061079), which is composed of chitosan polymer, poly-N-acetylglucosamine, in dry granules form are intended (Rx) to be used to achieve hemostasis in emergency situations for the temporary control of severe topical bleeding. CELOX Topical Hemostatic Granules OTC are indicated for the local management of bleeding such as lacerations, minor cuts and abrasions. CELOX Topical Hemostatic Granules and S.E.A.L. are equivalent products since they are both chitosan-based products and have the same indications.
- Alltracel Pharma Ltd Seal-On™ Hemostatic Powder Spray (K010933), which is a powder in an aerosol form composed of a polysaccharide, indicated for OTC use in the topical control of bleeding from minor cuts and abrasions of the skin surface. Seal-On™ Hemostatic Powder Spray and S.E.A.L. are equivalent products since they are both polysaccharide-based in a powder spray form in aluminum bottle for the topical control of bleeding.

The following table compares the S.E.A.L. to the predicate devices with respect to intended use, material characteristics, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

DEVICE COMPARISON CHART

Parameter	**Device**	**Predicate Device**	**Reference Predicative Device**
Trade name	S.E.A.L. Hemostatic Wound Spray	CELOX Topical Hemostatic Granules	Seal-On™ Hemostatic Powder Spray
Company Name	BC3 Technologies, Inc.	MEDTRADE PRODUCTS LIMITED	Alltracel Pharma Ltd.
510(k) #	K210751	K061079	K010933
Product Code	FRO	FRO	FRO
Hemostatic ingredient	Chitosan, a material consisting of cellulosic polymer, poly-N-acetyl-glucosamine	Chitosan polymer, poly-N-acetyl-glucosamine, in dry granules form	Oxidized cellulose
Auxiliary materials	Acid and propellant	Acid and undisclosed materials	Propellant and undisclosed materials
Physical composition	Powder in an aerosol form	Granules	Powder in an aerosol form
Particle shape and size	Irregular, less than 1 mm	Not disclosed	Irregular, less than 1 mm

Indications For Use	Prescription Use: S.E.A.L. Hemostatic Wound Spray is intended to be used to achieve hemostasis in emergency situations for the temporary control of severe topical bleeding. OTC: S.E.A.L. Hemostatic Wound Spray is indicated for the local management of bleeding such as lacerations, minor cuts and abrasions.	Intended (Rx) to be used to achieve hemostasis in emergency situations for the temporary control of severe topical bleeding. CELOX Topical Hemostatic Granules OTC are indicated for the local management of bleeding such as lacerations, minor cuts and abrasions.	Seal-On™ Hemostatic Powder Spray is indicated for OTC use in the topical control of bleeding from minor cuts and abrasions of the skin surface.
Packaging	Aluminum can	Aluminum pouch	Aluminum can
Sterilization Method	Gamma irradiation	Gamma irradiation	Gamma irradiation

S.E.A.L. has substantially equivalent indications to Seal-On™ Hemostatic Powder Spray (K010933) and CELOX Topical Hemostatic Granules (K061079) predicates in that they are indicated for topical application as an aid in the control of temporary external bleeding associated with minor to severely bleeding wounds.

S.E.A.L. and its predicate devices are all in the form of dry particles or granules from cellulosic polymers. S.E.A.L. and its predicate devices are all sterilized by irradiation.

S.E.A.L. and Seal-On™ Hemostatic Powder Spray are substantially equivalent in that they are both based on cellulosic polymers. Both contain cellulosic polymer as the hemostatic ingredient. Both contain particles and they are both packaged in aluminum packaging. Both devices are in the form of an aerosol. Both products use a propellant that belongs to the same class of non-flammable gases.

S.E.A.L. and CELOX Topical Hemostatic Granules are substantially equivalent in that they are both composed of chitosan. Both contain chitosan as the hemostatic ingredient. Both are in the form of dry particles/granules. They are both intended to be used (Rx) to achieve hemostasis in emergency situations for the temporary control of severe topical bleeding.

To prove that minor differences in ingredient do not raise different questions of safety and effectiveness and that S.E.A.L. is as safe and efficacious as its predicate devices, a series of tests were done as described below.

VII. PERFORMANCE DATA

Summary of the Non-clinical Testing:

In vitro testing

Performance data were provided in support of the substantial equivalence determination. The characteristics of the S.E.A.L. Hemostatic Wound Spray were substantially equivalent to the predicate device. S.E.A.L. is equivalent to CELOX in an in vitro coagulation test of porcine blood as determined by viscometry.

Animal studies

In vivo performance animal studies were done for S.E.A.L. to support substantial equivalence to Celox. A rat liver model and a standard swine hemorrhage model for efficacy assessment of topical hemostatic agents proved the substantial equivalence of S.E.A.L. and its predicate device Celox for both normal and coagulopathic animals.

In the rat liver model, S.E.A.L. showed biological safety, and no adverse effects were seen. S.E.A.L. was assessed as efficient hemostatic product with non-inferiority to Celox. The functional animal study conducted in the swine model confirmed the high efficacy of S.E.A.L. to achieve hemostasis, with no statistically significant differences in bleeding time, blood loss and survival time compared to Celox. Moreover, both gross necropsy and histopathology did not show any signs of tissue or organ damage related to the application of the device. Also, thromboemboli have not been developed in the surrounding tissues or other areas, and the risk of a thromboemboli migration to critical structures was also ruled out. S.E.A.L. proved to be as efficient and safe as Celox.

Summary of the Biocompatibility Testing:

The biocompatibility evaluation of the final, finished device was conducted in accordance with FDA guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"". S.E.A.L. is a device for breached or compromised surface with limited contact duration (< 24 h), and the testing included cytotoxicity, irritation, sensitization, acute systemic toxicity and material-mediated pyrogenicity.

The results of the biocompatibility testing are summarized in the following table:

Test	Results

Cytotoxicity Study Using the ISO Elution Method	Severe cell lysis or toxicity (MEM extract).
ISO Intracutaneous Irritation Study – Extract	Non-irritating (saline extract). Irritating (sesame oil extract).
Guinea Pig Maximization Test (ISO)	Non-sensitizing (saline and sesame oil extracts).
ISO Acute Systemic Toxicity Study in Mice	No systemic toxicity (saline and sesame oil extracts).
USP Rabbit Pyrogen Study, Material Mediated	Non-pyrogenic (saline extract).

The biocompatibility testing confirmed that S.E.A.L. is non-irritating (saline extract), non-sensitizing, has no systemic toxicity and is non-pyrogenic. The cytotoxicity testing showed severe cell lysis or toxicity, and the sesame oil extract (in contrast to saline) caused erythema and edema in the intracutaneous irritation testing.

The results of the cytotoxicity testing conducted at the contract labs by incubating fibroblast cells in the presence of extracts of S.E.A.L. chitosan can be attributed to the specific characteristics of chitosan which is not cytotoxic for fibroblasts but limits or prevents the fibroblastic growth. We conclude that the benefit of the efficient stop of severe bleeding significantly outweighs the potential risk of a reduced fibroblast proliferation for the limited time of contact with breached/compromised skin.

The erythema and edema observed after injection of sesame oil extracts of S.E.A.L. chitosan into the back of rabbits can be attributed to the presence of particles and agglomerates of large amount and size which will increase the risk of mechanical irritation in skin tissue. No such observations of erythema and edema were made with saline extracts in which the amount and size of particles is small. We conclude that the result of the irritation test can be attributed to the test conditions and interaction with the test medium and does not represent a risk for the limited time of use of S.E.A.L. as indicated.

None of the saline or sesame oil extracts tested for sensitization and acute systemic toxicity showed any signs of intolerance or toxicity, and we conclude that in the overall benefit/risk assessment S.E.A.L. can be considered as safe and as efficient as its predicate device as a material to stop severe bleeding in limited contact with the breached/compromised skin.

VIII. CONCLUSIONS

The S.E.A.L. Hemostatic Wound Spray, to be distributed by BC3 TECHNOLOGIES INC, is substantially equivalent in design and function to CELOX Topical Hemostatic Granules (K061079), manufactured by MedTrade Products and Seal-On™ Hemostatic Powder Spray (K010933), manufactured by Alltracel Pharma Ltd. The subject device has the same intended use, material composition, and similar characteristics and functional properties as the predicate devices. Moreover, documentation supplied in this submission demonstrates that any differences in their technological characteristics or materials do not raise any new questions of safety or effectiveness, and that the non-clinical data for the device supports the safety of the device.

Wayne L. Grube Jr.
CEO
BC3 Technologies
3701-A Southwestern Blvd - Baltimore, MD 21229
e: waynegrube@bc3tech.com - www.bc3tech.com
m: +1.443.204.7260 - p: +1.410.342.6100