Beeken Biomedical, LLC
% Susan Finneran
Regulatory Compliance Experts, Inc.
186 Old Farm Rd
Abington, Massachusetts 02351

April 21, 2023

Re: K160578
Trade/Device Name: Nustat XR
Regulatory Class: Unclassified
Product Code: QSY

Dear Susan Finneran:

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 29, 2016. 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

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

June 29, 2016

Beeken Biomedical, LLC
% Ms. Susan Finneran
Regulatory Compliance Experts, Inc.
186 Old Farm Road
Abington, Massachusetts 02351

Re: K160578
Trade/Device Name: Nustat XR
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 6, 2016
Received: May 9, 2016

Dear Ms. Finneran:

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)*
K160578

Device Name
Nustat Hemostatic Dressing

Indications for Use *(Describe)*
OTC:
NuStat is indicated to temporarily control bleeding in minor cuts, lacerations, punctures, abrasions and incisions.

Rx:
NuStat is a single-use hemostatic wound dressing applied externally with mechanical compression to temporarily control bleeding in lacerations, punctures, abrasions, surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries.

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."

Section 5- 510(k) Summary of Safety and Effectiveness

5.1 Statement	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92
5.2 Submitter	Beeken Biomedical, LLC. 292-G Page Street Stoughton, MA. 02072 **Establishment registration number**: 3009348684
5.3 Company Contact	Richard Kendall President & CEO Beeken Biomedical, LLC 292 Page Street, Unit G Stoughton, MA 02072
5.4 Device Name	**Proprietary Name:** Nustat Hemostatic Dressing **Common Name:** Hemostatic Wound Dressing **Classification Name:** Dressing, wound, Drug, FRO
5.5 Predicate Legally Marketed Devices	Nustat Hemostatic Dressing, which is the subject of this submission, is substantially equivalent to the previously cleared Nustat XR cleared via K142363. Reference predicate devices have also been included in table 5.1 below; HemCon Guardacare XR and the Quickclot Hemostatic Gauze, which were cleared via K103641 and K123387 respectively.

5.6 Device Description

The Nustat XR Hemostatic Dressing is a hemostatic wound dressing that composed of continuous filament silica and bamboo cellulose. The distribution of cellulose and silica fibers in each dressing is 65% silica fiber, 35% cellulose.

The dressings are available in various sizes in either Tyvek or LDPE pouched configurations and are available with or without the Radiopaque thread.

Size	**Packaging configuration**
2"x 36"	LDPE pouch
4 x 4"	LDPE pouch
12" x 12"	Tyvek pouch
3"x 48"	Tyvek pouch
4"x 48"	Tyvek pouch
6"x 60"	Tyvek pouch
4"x 8"	Tyvek pouch
8" x 12"	Tyvek pouch
2" x 2"	Tyvek pouch

The dressings are either z-folded or rolled into a medical grade Tyvek pouch or LDPE pouch which is then sterilized using gamma irradiation to a sterility assurance level of 10^{-6}.

The NuStat® range of hemostatic wound dressings have a number of hemostatic properties which enhance the ability of the dressing to temporarily control bleeding. The cellulose and continuous filament silica influence the contact activation pathway of the coagulation cascade by absorbing blood fluids, resulting in the localized concentration of platelets and clotting factors. The negatively charged fibers of the continuous filament silica simulate the negative ions secreted by activated platelets, which further influence the coagulation cascade. The radiopaque element allows for detection via x-ray.

5.7 Device Indications and Intended use

OTC:
NuStat is indicated to temporarily control bleeding in minor cuts, lacerations, punctures, abrasions and incisions.

Rx:
NuStat is a single-use hemostatic wound dressing applied externally with mechanical compression to temporarily control bleeding in lacerations, punctures, abrasions, surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries

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5.8 Performance Testing

Performance testing, including biocompatibility testing, laboratory verification testing, packaging validation, and sterilization validation has been completed to demonstrate substantial equivalence to the cited predicate device/ reference device.

Biocompatibility Testing
Biocompatibility testing was conducted in accordance with ISO 10993-1 and the following tests were conducted with passing results

ISO10993-5:Cytotoxicity (MEM Elution)
ISO 10993- 10: Sensitization (Guinea Pig Maximization)
ISO 10993-10:Irritation (Intracutaneous Reactivitiy Test)
ISO 10993-4: Hemolysis
ISO 10993-11: Acute Systemic Toxicity

Laboratory Verification Testing
Laboratory Verification Testing was conducted to verify the performance of the Nustat Hemostatic Dressing compared to the predicate device.

The objective of this evaluation was to compare the activated Partial Thromboplastin Time (aPTT) of the Nustat material to the aPTT of the predicate devices.
As part of this evaluation the aPTT time for the Nustat was compared to two predicate devices. The result demonstrated that the NuStat Dressing was substantially equivalent.

Age-Testing
Testing was completed to demonstrate that after subjecting the packaging and product to accelerated aging conditions that the package remained intact as demonstrated by package integrity testing conducted in accordance with ASTM F2096. Testing on the aged product was also tested for aPTT to demonstrate that the product was functioning and was substantially equivalent to the predicate device.

Radiopacity:
Imaging analysis was completed to demonstrate that the radiopaque thread would meet the requirements of ASTM F640-07.

Animal Testing (Swine femoral model):
A complex penetrating femoral artery groin injury was made using a 5.5mm vascular punch followed by 45 seconds of uncontrolled hemorrhage in 15 swine. The hemostatic dressings were randomized using a random sequence generator and then assigned to the animals.

Three minutes of manual pressure was applied with each agent after the free bleed. Primary end points included immediate hemostasis upon release of manual pressure (T0), hemostasis at 60 minutes, and re-bleeding during the 60-minute observation period.

Performance testing was adequate to demonstrate substantial equivalence of the subject device to the predicate for the conditions tested.

TABLE 5.1 TABLE OF SUSTANTIAL EQUIVALENCE

Feature	NuStat® Hemostatic Dressing Proposed Device	Nustat Hemostatic Dressing Primary predicate K142363	HemCon GuardaCare XR Reference Predicate K103641	QuickClot- Reference Predicate K123387
Intended Use	OTC: NuStat is a single-use hemostatic wound dressing applied externally with mechanical compression to temporarily control bleeding in lacerations, punctures, abrasions and incisions. Rx: NuStat is a single-use hemostatic wound dressing applied externally with mechanical compression to temporarily control bleeding in lacerations, punctures, abrasions, surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries.	OTC: Nustat is indicated to temporarily control bleeding in minor cuts, lacerations, punctures, abrasions, and incisions Rx: Nustat XR is a single-use hemostatic wound dressing applied externally with mechanical compression to temporarily control bleeding in lacerations, punctures, abrasions, and incisions.	HemCon GuardaCare XR is a hemostatic dressing intended for the temporary control of severely bleeding wounds such as surgical wounds and traumatic injuries.	Quickclot Hemostatic Dressing is intended for use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions. It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries

Feature	NuStat® Hemostatic Dressing Proposed Device	Nustat Hemostatic Dressing Primary predicate K142363	HemCon GuardaCare XR Reference Predicate K103641	QuickClot- Reference Predicate K123387
Mechanism of Action for Hemostasis	Knitted material forms a physical structure which acts as a fluid absorbent, aggregating platelets and Red Blood Cells Properties of the continuous filament silica trigger an electrostatic interaction when in contact with blood to promote clotting.	Knitted material forms a physical structure which acts as a fluid absorbent, aggregating platelets and Red Blood Cells Properties of the continuous filament silica trigger an electrostatic interaction when in contact with blood to promote clotting.	Knitted material forms a physical structure which acts as a fluid absorbent, aggregating platelets and Red Blood Cells Properties of the chitosan trigger an electrostatic interaction when in contact with blood to promote clotting.	Knitted material forms a physical structure which acts as a fluid absorbent, aggregating platelets and Red Blood Cells Properties of the kaolin, a mineral which triggers electrostatic interaction when in a contact with blood to promote clotting
Method of Use	Placed or packed over wound. Compressed until bleeding is controlled. Removed within 24 hours.	Placed or packed over wound. Compressed until bleeding is controlled. Removed within 24 hours.	Placed or packed over wound. Compressed until bleeding is controlled. Removed within 24 hours.	Placed or packed over wound. Compressed until bleeding is controlled. Removed within 24 hours.
Composition	Knitted cellulose and continuous filament silica Cellulose (rayon, edge sealant) Optional Radiopaque element - Polypropylene thread coated with barium sulfate	Knitted cellulose and continuous filament silica Cellulose (rayon, edge sealant) Optional Radiopaque element - Polypropylene thread coated with	Knitted cellulose and polyester/ rayon blend coated with Chitosan Radiopaque element	Knitted cellulose and kaolin. Radiopaque element
Form Factor	Folded or rolled 4” x 4” , 2” x 36” 12 x 12” 3” x 48” 4”x 48” 6” x 60” 4” x 8” 8” x12” 2” x 2”	Folded or rolled 4” x 4” 2” x 36” 12 x 12” 3” x 48” 4”x 48” 6” x 60” 4” x 8” 8” x12”	Rectangular, z-folded 8-ply 2” x 2” 8-ply 4” x 4” 4” x 2 yrds, Z folded 4”x 4”	Available in 1 inch and 5/8th inch diameter in the following configurations: 2”x 2 , 4”x 4”, 12”x 12”, 3”x 4 yrds, 4” x4 yrds.
Packaging	LDPE or Tyvek pouch	Tyvek peel pouch	PET Foil peel pouch	Pouch, not specified
Sterilization Method	Gamma Irradiation	Gamma irradiation	Gamma Irradiation	Gamma irradiation