September 25, 2019

Beeken Biomedical, LLC
℅ Mary McNamara
Vice President of Regulatory Affairs
Alira Health
1 Grant Street, Suite 400
Framingham, MA 01702

Re: K183190
Trade/Device Name: NuStat
Regulation Number: 21 CFR 878.4454
Regulation Name: Non-Absorbable, Hemostatic Gauze for Temporary Internal Use
Regulatory Class: Class II
Product Code: POD
Dated: August 29, 2019
Received: August 30, 2019

Dear Mary McNamara:

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,

For Cindy Chowdhury, Ph.D., M.B.A.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183190

Device Name
NuStat

Indications for Use *(Describe)*
NuStat is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds 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.

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510(k) Summary

510(k) Number:	K183190
Submitter:	Beeken Biomedical, LLC 378 Page Street, Suite 201 Stoughton, MA 02072
Contact Person:	Richard A. Kendall
Preparation Date:	September 23, 2019
Device Name:	NuStat®
Device Classification:	Common Name: Temporary, Internal Use Hemostatic Wound Dressing Generic Name: Non-absorbable, hemostatic gauze for temporary internal use Device Classification: Class II Regulation Number: 21 CFR 878.4454 Product Code: POD
Special Controls:	Complies with the Non-absorbable, hemostatic gauze for temporary internal use as identified in 21 CFR 878.4454
Intended Use / Indications for Use:	NuStat is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.
Device Description:	The NuStat is a hemostatic wound dressing that is composed of continuous filament silica and bamboo cellulose rayon fiber and is provided with radiopaque thread. The distribution of cellulose and silica fibers in each dressing is 65% silica fiber and 35% bamboo cellulose rayon fiber. The dressings are available in various sizes and provided sterile in either foil, Tyvek, or LDPE pouched configurations. The NuStat hemostatic wound dressings have a number of hemostatic properties that enhance the ability of the dressing to temporarily control bleeding. NuStat Hemostatic Dressing's mode of action is via absorption of fluid, which results in a physical aggregation of blood cells and clotting factors at the site of application. The radiopaque element allows for detection via x-ray.
Predicate Device:	Z-Medica, LLC's D2 Dressing (DEN160012), decision date June 30, 2017.

Reference Device:	Beeken Biomedical, LLC's NuStat XR (K160578), decision date June 29, 2016.
Special Controls:	The performance testing demonstrates the device performs as intended under anticipated conditions of use, per the special controls for the non-absorbable, hemostatic gauze for temporary internal use as identified in 21 CFR 878.4454
Mechanism of Action:	The principle of operation for NuStat is via absorption of fluid, resulting in a physical aggregation of blood cells and clotting factors. The cellulose component absorbs excess fluid which results in a physical aggregation of blood cells and clotting factors at the site of application.
Comparison of Technological Characteristics:	Fundamental scientific technology, including design, are equivalent to the predicate device D2 Dressing (DEN160012) and identical to reference device NuStat XR (K160578). The key technological and performance similarities examined among devices are as follows: Mechanism of Action - Equivalent to the predicate device and identical to the reference device. Packaging Materials – Identical to the reference device and equivalent to the predicate device. Sterilization Method - Identical to the predicate and reference devices.
Substantial Equivalence:	Predicate device, Z-Medica, LLC's D2 Dressing (DEN160012), is a class II device per decision date June 30, 2017. Reference device, Beeken Biomedical, LLC's NuStat XR (K160578) is the exact same identical device as the subject device. Substantial equivalence to the predicate device is based on intended use, physical and technological characteristics, and comparative device information. This submission seeks to expand the Rx indication for use for the NuStat device. Table 1 below demonstrates the substantial equivalence between NuStat and the predicate and reference device.

Substantial Equivalence				
	Subject Device	Predicate Device	Reference Device	Equivalence
Applicant	Beeken Biomedical, LLC	Z-Medica, LLC	Beeken Biomedical, LLC	N/A
Device Name	NuStat	D2 Dressing	NuStat XR	N/A
510(k)/De Novo Number	TBD	DEN160012	K160578	N/A
Decision Date	TBD	June 30, 2017	June 29, 2016	N/A
Device Classification Name	Non-absorbable, hemostatic gauze for temporary internal use;	Non-absorbable, hemostatic gauze for temporary internal use	Dressing, Wound, Drug	Equivalent
Regulation Number	878.4454;	878.4454	Unclassified	Equivalent
Product Code	POD	POD	FRO	Equivalent
510(k) Review Panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	Identical

Device Description	The NuStat is a hemostatic wound dressing that is composed of continuous filament silica and bamboo cellulose with radiopaque thread. The distribution of cellulose and silica fibers in each dressing is 65% silica fiber and 35% cellulose. The dressings are available in various sizes in either Tyvek or LDPE pouched configurations. The NuStat range of hemostatic wound dressings have a number of hemostatic properties that enhance the ability of the dressing to temporarily control bleeding. The radiopaque element allows for detection via x-ray. The principle of operation for NuStat is via absorption of fluid, resulting in a physical aggregation of blood cells and clotting factors. The cellulose component absorbs excess fluid which results in a physical aggregation of blood cells and clotting factors at the site of application.	QuikClot Control+ consists of a white to off-white to yellow sterile, x-ray detectable hemostatic dressing and is packaged for aseptic removal. QuikClot Control+ is impregnated with kaolin, a naturally occurring, inorganic mineral that accelerates the body's natural clotting process. It's the same active ingredient used in QuikClot Combat Gauze®. Because kaolin contains no animal or human proteins, no thrombin, fibrinogen, botanicals, or shellfish products, there is no risk of allergic responses. Biocompatibility studies have shown that it is safe and has no negative effect on tissues. Integrated double X-ray indicators facilitate detection and removal, reducing the risk of lost or retained product.	The NuStat is a hemostatic wound dressing that is composed of continuous filament silica and bamboo cellulose, and are available with or without radiopaque thread. The distribution of cellulose and silica fibers in each dressing is 65% silica fiber and 35% cellulose. The dressings are available in various sizes in either Tyvek or LDPE pouched configurations. The NuStat range of hemostatic wound dressings have a number of hemostatic properties that 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.	Equivalent. Both are hemostatic wound dressings that utilize a matrix of fibers to absorb blood and accelerate the clotting process. Both use hemostatic material that may enhance hemostasis by physical means. This difference does not raise any new issues of safety or effectiveness.

Intended Use / Indications for Use	Rx: NuStat is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.	Rx: D2 Dressing is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.	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.	Equivalent. Subject device uses both intended use / indications for use of predicate and reference device. Additional testing was performed in support of expanding the Rx indication for use in this submission.
Mechanism of Action	The gauze is knit from silica and cellulose fibers, hemostatic material that may enhance hemostasis by physical means. Knitted material forms a physical structure which acts as a fluid absorbent, aggregating platelets and red blood cells.	The gauze is impregnated with kaolin, hemostatic material that may enhance hemostasis by physical means.	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.	Equivalent. The devices share the same physical mechanism of action; contact activation of the clotting cascade. The predicate, reference, and subject devices are constructed with hemostatic material which may enhance hemostasis by physical means. This difference does not raise any new issues of safety or effectiveness.

Target Population	Rx: Patients displaying class III or class IV bleeding.	Rx: Patients displaying class III or class IV bleeding.	Rx: Patients displaying bleeding in lacerations, punctures, abrasions, surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries. OTC: Patients displaying minor cuts, lacerations, punctures, abrasions and incisions.	Equivalent. The subject device combines the target population of the predicate and reference device as appropriate to the Rx indication. This difference does not raise any new issues of safety or effectiveness.
Anatomical Site	Rx: Internal organ space, surgical wounds, and traumatic injuries.	Rx: Internal organ space, surgical wounds, and traumatic injuries.	Rx: Bleeding in lacerations, punctures, abrasions, surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries. OTC: Minor cuts, lacerations, punctures, abrasions and incisions.	Equivalent. The subject device combines the anatomical sites of the predicate and reference device as appropriate to the Rx indication. This difference does not raise any new issues of safety or effectiveness.
Materials	65% silica fiber 35% cellulose rayon fiber PP-BaSO4 radiopaque thread	Hydrophilic gauze impregnated with kaolin Radiopaque material	65% silica fiber 35% cellulose rayon fiber Optional PP-BaSO4 radiopaque thread	Equivalent. Subject, predicate, and reference devices contain hemostatic material. Subject and predicate devices provide radiopaque material.

Physical Presentation	Knit gauze	Non-woven gauze	Knit gauze	Equivalent. Knit gauze is one continuous looped yarn to form a fabric matrix. Woven gauze is multiple yarns crossing each other to form a fabric matrix. Subject, predicate, and reference devices are non-woven dressings that create a fabric matrix with space between the yarns to absorb blood. This difference does not raise any new issues of safety or effectiveness.
Device Dimensions	2” x 2” 2” x 36” 3” x 48” 4” x 4” 4” x 8” 4” x 48” 6” x 60” 8” x 12” 12” x 12”	3” x 72” 5” x 5” 8” x 8” 12” x 12”	2” x 2” 2” x 36” 3” x 48” 4” x 4” 4” x 8” 4” x 48” 6” x 60” 8” x 12” 12” x 12”	Equivalent. Subject and reference devices have the exact same dimension configurations. Subject device offers similar dimensions as the predicate device dimensions. This difference does not raise any new issues of safety or effectiveness.
Sterilization Method	Gamma radiation	Gamma radiation	Gamma radiation	Identical.
Packaging	Tyvek or LDPE pouch in a paperboard box	Foil peel pouch in a paperboard box	Tyvek or LDPE pouch in a paperboard box	Equivalent. These packaging materials are common with these devices. This difference does not raise any new issues of safety or effectiveness.
Shelf Life	1 year	Unknown	3 years for Tyvek 5 years for LDPE	The subject and reference devices have the exact same shelf life. The shelf life of the predicate device is unknown.

Performance Testing: The performance testing demonstrates the device performs as intended under anticipated conditions of use, per the special controls for the non-absorbable, hemostatic gauze for temporary internal use as identified in 21 CFR 878.4454 and is described below:

- Hemostasis: Assessed in a Pilot study and Pivotal GLP study of liver resection in the pig model. Hemostasis of a moderate to significant bleeding surface was achieved within 3 minutes, substantially equivalent to the predicate device.
- Radiographic Detection: Assessed in a Pilot study and Pivotal GLP study of liver resection in the pig model. The device was rated as being easily visualized radiographically at the time of placement and at 48 hours.
- Vascular obstruction and downstream embolization: Assessed in a Pilot study and Pivotal GLP study of liver resection in the pig model. No evidence of vascular obstruction or embolization was observed in either study. In the GLP study, this was substantially equivalent to the predicate device.
- Sterility: Validated sterilization testing shows that the device is sterile. Performance testing was assessed in a Pilot study and Pivotal GLP study of liver resection in the pig model. No evidence of infection was noted in either study.
- Biocompatibility: The device was tested per ISO 10993-1 a device with prolonged duration of patient contact (>24 hours to 30 days) in contact with the blood path and circulating blood. The results show the device is biocompatible.
- Cytotoxicity: Performed per ISO 10993-5 (ISO elution method), device is considered non-cytotoxic.
- Sensitization: Performed per ISO 10993-10 (Magnusson-Kligman method), device is considered non-sensitizing.
- Irritation: Performed per ISO 10993-11 (intracutaneous reactivity testing), device is considered non-irritant.
- Systemic toxicity, acute: Performed per ISO 10993-11 (acute systemic toxicity in mice), device showed no acute systemic toxicity.
- Pyrogenicity: Performed per ISO 10993-11 and USP <151>, (rabbit pyrogen test) device is considered non-pyrogenic.
- Endotoxin: Performed per LAL Kinetic Turbidimetric Assay, device conforms to FDA and USP requirements for end-product release of medical devices.
- Interaction with blood: Performed per ISO 10993-4 (SC5b-9 Complement Assay, device performed as expected for a hemostatic device; activated complement.
- Sub-acute systemic toxicity: Performed per ISO 10993-11 (implantation in rabbit abdomen), device showed no signs of systemic toxicity/
- Sub-chronic systemic toxicity: Performed per ISO 10993-11 (Pivotal Study "Evaluation of the NuStat Trauma Pad XR Dressing When Applied to a Linear Resection Defect, 48 Hours and 28 Day"- FP-SS), device showed no signs of subchronic toxicity.

- Genotoxicity: Performed per ISO 10993-5 (Ames test, Mouse lymphoma assay), device showed no signs of genotoxicity.
- Local effects after implantation: Performed per ISO 10993-6 (rabbit muscle implant and Pivotal GLP Study. In the rabbit muscle study the device was considered an irritant, as expected for a non-absorbable device. In the pivotal study, the device showed no adverse events.
- Inflammation, adhesions, systemic and local toxicity: Performed per ISO 10993-6, 10993-11 and assessments customized to the intended use in the Pivotal GLP study (Pivotal Study "Evaluation of the NuStat Trauma Pad XR Dressing When Applied to a Linear Resection Defect, 48 Hours and 28 Day"- FP-SS). The device showed no signs of systemic, or local toxicity. Inflammation and adhesions associated with the device were as expected for this type of surgery (laparotomy and liver resection) and were substantially equivalent to those of the predicate device.
- Pilot Pig Study- "Pilot Study to Develop and Refine a Survival Mode of Severe Hemorrhage for the Evaluation of the NuStat Internal Hemostatic Dressing (NuStat XR)" – ANS 2319
- Pivotal Pig Study- "Evaluation of the NuStat Trauma Pad XR Dressing When Applied to a Linear Resection Defect, 48 Hours and 28 Day"- FP-SS
- In-vitro clot assessment: Assessed by testing PT and aPTT in bench tests. Device accelerated clotting times from baseline.
- Particulate release testing: Tested under worst-case scenario, the device released silica particulates in quantities that were too numerous to count. This was substantially equivalent to the predicate device. Particulate sizes were not enumerated for either device.
- Swell percent: Tested as part of absorption capacity. The swell of the device was minimal.
- Tensile strength testing: Tested and passed according to specifications
- Tear strength: Tested and passed according to specifications
- Stability: Testing was performed to support a one-year expiration date

Conclusion: The subject device is equivalent to the predicate device and identical to the reference device. These conclusions are based upon the facts that the subject device is the exact same, identical device as the reference device, and the subject device has identical intended use and equivalent technological characteristics as the predicate device. These differences do not raise new types of questions of safety and effectiveness.