April 12, 2018

StatGuard, LLC
Gary Mills
President
7555 Cason Lane
Gladstone, Oregon 97027

Re: K172155
Trade/Device Name: StatGuard Hemostatic Patch, StatGuard Hemostatic Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 1, 2018
Received: March 6, 2018

Dear Gary Mills:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172155

Device Name
StatGuard® Hemostatic Patch and StatGuard® Hemostatic Dressing

Indications for Use *(Describe)*

The StatGuard® Hemostatic Patch is indicated for use, under the direction of a healthcare professional, in the management and control of surface bleeding from wounds, including vascular access sites.

The StatGuard® Hemostatic Dressing is indicated for use, under the direction of a healthcare professional, in the management and control of surface bleeding from wounds, including vascular access sites.

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.

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510(k) Summary
K172155

Submitter's name: StatGuard, LLC
7555 Cason Lane
Gladstone, OR 97027

Contact name and address: Gary Mills, President
7555 Cason Lane
Gladstone, OR 97027
(503-657-4059)

Date summary prepared: 12 March 2018

Device name:

Proprietary name:	StatGuard® Hemostatic Patch StatGuard® Hemostatic Dressing
Common or usual name:	Wound Dressing
Classification:	Unclassified
Classification name:	Dressing, Wound, Drug
Classification product code:	FRO

Legally marketed devices for substantial equivalence comparison:

The primary predicate device for this submission is the AnsCare ChitoClot Gauze from BenQ Materials Corp. (K143462). Additional predicate devices are identified as ChitoGauze from HemCon Medical Technologies, Inc. (K090026), and CELOX Vascular from Medtrade Products Ltd. (K093519).

Description of the device:

The StatGuard® Devices are based on a non-woven fabric derived from chitosan fibers. The hemostatic properties of chitosan are widely recognized in the biomedical field. When applied directly on a wound with firm pressure, the chitosan material will turn into a gel-like condition to absorb the blood. It promotes control of moderate to severe wound bleeding and exudates absorption, and promotes coagulation. The dressing provides a barrier to bacterial penetration through the dressing and has antibacterial properties that reduce bacterial growth within the dressing. No clinical studies have been conducted on the subject device and the clinical benefit of this antibacterial property is unknown.

The StatGuard® Hemostatic Patch is made of the non-woven fabric derived from chitosan fibers with a polyurethane backing. The StatGuard Hemostatic Patch is a 2" by 2" dressing that is placed directly over a wound for external control of bleeding. The Patch may be used with patients following a vascular procedure, hemodialysis, or other procedures resulting in bleeding wounds.

The StatGuard Hemostatic Patch is individually packaged in a peelable foil pouch and is sterilized by gamma irradiation. The hemostatic properties of chitosan enhance the ability of the StatGuard Hemostatic Patch to control bleeding.

The StatGuard® Hemostatic Dressing is made of the non-woven fabric derived from chitosan fibers with the addition of a backing that extends past the margins of the patch, with a pressure sensitive adhesive to adhere to the patient. The StatGuard Hemostatic Dressings are provided in various sizes. The Dressing may be used with patients who have wounds that are bleeding or may be prone to bleeding. The hemostatic properties of chitosan enhance the ability of the StatGuard Hemostatic Dressing to control bleeding. The StatGuard® Hemostatic Dressings are packaged in a polyester laminated film pouch. Sterilization is by gamma radiation.

The StatGuard® Hemostatic Dressings are initially provided in sizes as shown:

Dressing	Chitosan pad size	Overall size
StatGuard® Hemostatic Dressing, Small	2 cm x 3 cm	4 cm x 6 cm
StatGuard® Hemostatic Dressing, Regular	4 cm x 6 cm	8 cm x 10 cm
StatGuard® Hemostatic Dressing, Large	5 cm x 7 cm	10 cm x 12 cm

Intended use of the device:

The StatGuard® Hemostatic Patch is indicated for use, under the direction of a healthcare professional, in the management and control of surface bleeding from wounds, including vascular access sites.

The StatGuard® Hemostatic Dressing is indicated for use, under the direction of a healthcare professional, in the management and control of surface bleeding from wounds, including vascular access sites.

Technological characteristics:

The device features of the StatGuard® Hemostatic Patch and of the StatGuard® Hemostatic Dressing are similar to predicate devices, in that all use the hemostatic properties of chitosan to promote hemostasis of a bleeding wound. The Hemostatic Patch is a pad with a backing layer adhered on the back of the pad, only. The Hemostatic Dressing is a pad with an adhesive backing that extends past the margins of the patch to provide adhesion to the patient. Release liners are removed as the dressing is applied to the patient.

Non-clinical Testing:

Biocompatibility Testing:

- Cytotoxicity
- Intracutaneous Irritations
- Skin Irritation
- Skin Sensitization
- Acute Intravenous Systemic Toxicity
- Acute Intraperitoneal Systemic Toxicity
- Endotoxin
- Hemolysis
- Rabbit Pyrogen

Bench Performance Testing Including Function Testing:

- Platelet Aggregation
- Thromboelasticity
- Antibacterial within the dressing
- Microbial Barrier
- Heavy Metal
- Protein Content
- Residual Ethanol
- Sterilization Validation
- Package Validation
- Shelf Life

Animal Test:

- *In-vivo* Hemostasis

StatGuard® Hemostatic Patches and Hemostatic Dressings were subjected a series of non-clinical studies. All the test results demonstrate that the submitted devices meet the requirements of the pre-defined acceptance criteria, specifications, and intended uses and are substantially equivalent to the predicate devices. Biocompatibility testing included cytotoxicity, sensitization, irritation, acute system toxicity, hemolysis, and pyrogenicity was conducted in accordance with ISO 10993. Antibacterial activity has been demonstrated within the dressing per AATCC 100,

Assessment of Antibacterial Finishes on Textile Materials. Microbial Barrier performance testing has also been conducted.

The StatGuard® Hemostatic Patches and StatGuard® Hemostatic Dressings exhibited substantially equivalent efficacy in the ability to control bleeding to their predicate, AnsCare ChitoClot Gauze. All tests demonstrated the materials and processes used in the design and manufacture of the devices are non-cytotoxic, non-sensitizing, non-irritants and non-pyrogenic. The StatGuard® Hemostatic Patch and StatGuard® Hemostatic Dressing demonstrated microbial barrier properties.

The gauze used in the StatGuard® Hemostatic Patch and StatGuard® Hemostatic Dressing was tested for antibacterial effectiveness against gram+ and gram- bacterial strains per *in-vitro* testing based on a modified AATCC Test Method 100:

Microorganism:	Gram Stain	Log Reduction
Micrococcus luteus ATCC 4698	+	> 4
Streptococcus mutans ATCC 25175	+	> 4
Streptococcus pneumoniae ATCC 33400	+	> 4
Streptococcus pyogenes ATCC 12344	+	> 4
Acinetobactor baumannii ATCC 19606	–	> 4
Klebsiella pneumoniae ATCC 4352	–	> 4
Proteus mirabilis ATCC 25933	–	> 4
Pseudomonas aeruginosa ATCC 9027	–	> 4
Escherichia coli ATCC 8739	–	3.88 *

* Test results for E. coli did not meet the > 4 log reduction acceptance criteria.

The data demonstrates the bacteriostatic and bactericidal effectiveness within the dressing of the StatGuard® Hemostatic Patch and the StatGuard® Hemostatic Dressing.

Sterility Testing:

The StatGuard® Hemostatic Patch and the StatGuard® Hemostatic Dressing are gamma radiation sterilized. Sterility testing was conducted per ISO 11137 requirements to demonstrate a 10^{-6} SAL using the VDmax25 method.

Substantial Equivalence Comparison:

	Submitted Device	Predicate Device	Predicate Device	Predicate Device
Item	StatGuard® Hemostatic Patch and Dressing	AnsCare ChitoClot Gauze (BenQ Materials Corp.)	ChitoGauze (HemCon Medical Technologies, Inc.)	CELOX Vascular (Medtrade Products, LTD)
K number	K172155	K143462	K090026	K093519
Classification	Unclassified	Unclassified	Unclassified	Unclassified
Product Code	FRO	FRO	FRO	FRO
Combination Product	No	No	No	No
Common or Usual Name	Wound Dressing	Dressing	Dressing	Dressing
Applicable Device Standards	None	None	None	None
Prescriptive Use	Yes	Yes	Yes	Yes
Indications for Use (prescriptive use)	The StatGuard® Hemostatic Patch is indicated for use, under the direction of a healthcare professional, in the management and control of surface bleeding from wounds, including vascular access sites. The StatGuard® Hemostatic Dressing is indicated for use, under the direction of a healthcare professional, in the management and control of surface bleeding from wounds, including vascular access sites.	For use as a temporary external dressing to control moderate to severe bleeding and manage external abrasions, lacerations.	ChitoGauze is a hemostatic dressing for the external, temporary control of severely bleeding wounds.	CELOX Vascular is indicated for the local management and control of surface bleeding from vascular access sites, percutaneous catheters or tubes utilizing introducer sheaths up to 16 French.
Physical Composition	Soft absorbent, non-woven gauze, with backing material or with adhesive dressing	Soft absorbent, non-woven gauze	Polyester/rayon blend non-woven medical grade gauze coated with chitosan	CELOX hemostatic granules heat bonded onto a viscous sheet
Requires separate wrap or adhesive	Yes (patch) No (dressing)	Yes	Yes	Yes
Hemostatic Material	Chitosan (Poly N-acetyl-glucosamine)	Chitosan (Poly N-acetyl-glucosamine)	Chitosan	Chitosan
Chitosan Form	Non-woven fabric derived from chitosan fibers	Non-woven fabric derived from chitosan fibers	Coated on gauze	Granules
Antibacterial within the dressing	Yes	Not claimed	Yes	Not claimed
Sterility	Gamma-Sterilized	Gamma-Sterilized	Gamma-Sterilized	Gamma-Sterilized
Packaging	Foil pouch (patch) Polyester pouch (dressing)	Foil pouch	Foil pouch	Foil pouch
Duration of use	Temporary	Temporary	Temporary	Temporary
Specifications	2” x 2” (patch) various (dressing)	Various widths and roll lengths	4” x 4 yds., z-folded	2” x 2”

Summary of Substantial Equivalence:

The StatGuard® Hemostatic Patch and the StatGuard® Hemostatic Dressing passed all testing and are as safe and effective and substantially equivalent to the indicated predicate devices. Any differences in technological characteristics between the StatGuard® Hemostatic Patch and the StatGuard® Hemostatic Dressings and the predicate devices do not raise new questions about safety and effectiveness.