August 29, 2024

Stryker Spine
Fiorella Lopardo
Staff Regulatory Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K242280
Trade/Device Name: Vitoss® BiModal Bioactive Bone Graft Substitute Foam Strip
Vitoss® BiModal Bioactive Bone Graft Substitute
Vitoss BBTrauma® Bioactive Bone Graft Substitute
Vitoss® BA2X Bioactive Bone Graft Substitute
Vitoss® Bioactive Bone Graft Substitute Pack
Vitoss® Bioactive Bone Graft Substitute
Vitoss® Foam Bone Graft Substitute
Vitoss® Bone Graft Substitute Filled Canister
Vitoss® Bone Graft Substitute
Vitoss® Bone Graft Substitute - Synthetic Cancellous Chips

Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: August 1, 2024
Received: August 2, 2024

Dear Fiorella Lopardo:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2024.08.29 15:27:32 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242280

Device Name

Vitoss® BiModal Bioactive Bone Graft Substitute Foam Strip;
Vitoss® BiModal Bioactive Bone Graft Substitute ;
Vitoss BBTrauma® Bioactive Bone Graft Substitute ;
Vitoss® BA2X Bioactive Bone Graft Substitute ;
Vitoss® Bioactive Bone Graft Substitute Pack;
Vitoss® Bioactive Bone Graft Substitute;
Vitoss® Foam Bone Graft Substitute ;
Vitoss® Bone Graft Substitute Filled Canister ;
Vitoss® Bone Graft Substitute;
Vitoss® Bone Graft Substitute - Synthetic Cancellous Chips

Indications for Use *(Describe)*

Vitoss® BA2X Bioactive Bone Graft Substitute, Vitoss BBTrauma® Bioactive Bone Graft Substitute, Vitoss® BiModal Bioactive Bone Graft Substitute, Vitoss® BiModal Bioactive Bone Graft Substitute Foam Strip
These implants are intended for use as bone void fillers for voids or gaps that are not intrinsic to the stability of the bony structure.

They are indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone.

The implants are intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, pelvis and posterolateral spine) and may be combined with saline, autogenous blood, and/or bone marrow. Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.

Vitoss® Bioactive Bone Graft Substitute, Vitoss® Bioactive Bone Graft Substitute Pack
Vitoss® Bioactive Foam Bone Graft Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Vitoss® Bioactive Foam is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. Vitoss® Bioactive Foam Bone Graft Substitute is intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, pelvis, and spine, which includes posterolateral fusion procedures) and may be combined with saline, autogenous blood, and/or bone marrow. Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.

Vitoss® Bone Graft Substitute, Vitoss® Bone Graft Substitute - Synthetic Cancellous Chips, Vitoss® Foam Bone Graft Substitute, Vitoss® Bone Graft Substitute Filled Canister
These implants are intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure.

These implants are indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. These implants should not be used to treat large defects that in the surgeon’s opinion would fail to heal spontaneously.

These implants are intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis) and may be combined with autogenous blood and/or bone marrow. Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.
The Vitoss® Foam family of products may be mixed with saline in addition to autogenous blood or bone marrow.

The Vitoss® Filled Canister is intended for use as a piston syringe system for the aspiration of autogenous blood and/or bone marrow. This canister provides the surgeon with a convenient way to mix autogenous blood with Vitoss® and deliver the material to the orthopaedic surgical site.

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.

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510(k) Summary	
Submitter:	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person :	Name: Fiorella Lopardo Phone: 954-871-5460 Email: fiorella.lopardo@stryker.com Secondary Contact: Name: Shraddha Moore Phone: 201-831-5804 Email: shraddha.more@stryker.com
Date Prepared:	August 29, 2024
Trade Names:	1. Vitoss® BiModal Bioactive Bone Graft Substitute Foam Strip 2. Vitoss® BiModal Bioactive Bone Graft Substitute 3. Vitoss BBTrauma® Bioactive Bone Graft Substitute 4. Vitoss® BA2X Bioactive Bone Graft Substitute 5. Vitoss® Bioactive Bone Graft Substitute Pack 6. Vitoss® Bioactive Bone Graft Substitute 7. Vitoss® Foam Bone Graft Substitute 8. Vitoss® Bone Graft Substitute Filled Canister 9. Vitoss® Bone Graft Substitute 10. Vitoss® Bone Graft Substitute - Synthetic Cancellous Chips
Common Name:	Resorbable Calcium Salt Bone Void Filler Device
Proposed Class:	Class II
Classification Name:	Filler, Bone Void, Calcium Compound (21 CFR 888.3045)
Product Code:	MQV
Predicate Devices:	**Primary Predicate:** Vitoss BiModal Bone Graft Substitute Foam Strip (K153608) **Additional Predicates:** Vitoss BA Bimodal Bioactive Bone Graft Substitute (K103173) FM-02 Bone Graft Substitute (K102545) Vitoss Bioactive Foam Bone Graft Substitute Pack, Vitoss Bioactive Foam Bone Graft Substitute, Vitoss Foam Bone Graft Substitute, Vitoss Bone Graft Substitute Filled Canister, Vitoss Bone Graft Substitute (K083033)

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Device Description:	Vitoss® Bone Graft Substitutes are intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure in the skeletal system. Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.
Indications for Use:	**Vitoss® BA2X Bioactive Bone Graft Substitute, Vitoss BBTrauma® Bioactive Bone Graft Substitute, Vitoss® BiModal Bioactive Bone Graft Substitute, Vitoss® BiModal Bioactive Bone Graft Substitute Foam Strip** These implants are intended for use as bone void fillers for voids or gaps that are not intrinsic to the stability of the bony structure. They are indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. The implants are intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, pelvis and posterolateral spine) and may be combined with saline, autogenous blood, and/or bone marrow. Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process. **Vitoss® Bioactive Bone Graft Substitute, Vitoss® Bioactive Bone Graft Substitute Pack** Vitoss® Bioactive Foam Bone Graft Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Vitoss® Bioactive Foam is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. Vitoss® Bioactive Foam Bone Graft Substitute is intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, pelvis, and spine, which includes posterolateral fusion procedures) and may be combined with saline, autogenous blood, and/or bone marrow. Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process. **Vitoss® Bone Graft Substitute, Vitoss® Bone Graft Substitute - Synthetic Cancellous Chips, Vitoss® Foam Bone Graft Substitute, Vitoss® Bone Graft Substitute Filled Canister** These implants are intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. These implants are indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. These implants should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously. These implants are intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis) and may be combined with autogenous blood and/or bone marrow. Following placement in the bony

510(k) Summary	
	void or gap, the scaffold resorbs and is replaced with bone during the healing process. The Vitoss® Foam family of products may be mixed with saline in addition to autogenous blood or bone marrow. The Vitoss® Filled Canister is intended for use as a piston syringe system for the aspiration of autogenous blood and/or bone marrow. This canister provides the surgeon with a convenient way to mix autogenous blood with Vitoss® and deliver the material to the orthopaedic surgical site.
Summary of the Technological Characteristics	The subject devices have similar technological characteristics as their predicate devices. Changes implemented since the last clearance of the subject devices were assessed and detailed in this submission. Minor differences in technological characteristics of the subject devices do not impact safety and efficacy of the devices. Therefore, the fundamental scientific technology of the subject devices is the same as previously cleared devices.
Summary of the Performance Data	The device materials have been analyzed in accordance with ASTM F2503 to confirm they meet the definition of MR Safe.
Conclusion	The subject devices have the same intended use with minor differences in the indications for use and technological characteristics as the predicate devices. Per the assessments detailed in this submission, the minor differences in indications for use and technological characteristics of the subject devices and updates to the labeling do not impact safety and efficacy of the devices. Therefore, the subject devices are substantially equivalent to their predicate devices.