April 24, 2026

Stryker Spine
Kristina Daoud
Senior Regulatory Affairs Specialist
2 Pearl Ct.
Allendale, New Jersey 07401

Re: K261008
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 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

Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: March 26, 2026
Received: March 26, 2026

Dear Kristina Daoud:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2026.04.24 09:36:42 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261008	?

Please provide the device trade name(s). ?

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 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

Please provide your Indications for Use below. ?

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, intervertebral disc space, and posterolateral spine) and may be combined with saline, autogenous blood, and/or bone marrow. These osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of traumatic injury to the bone. When used in intervertebral body fusion procedures with an intervertebral body fusion device cleared by FDA for use with a bone void filler, Vitoss® can be mixed with saline, autogenous blood, bone marrow, and/or used on its own. 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

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 intervertebral disc space and posterolateral fusion procedures) and may be combined with saline, autogenous blood, and/or bone marrow. These osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of traumatic injury to the bone. When used in intervertebral body fusion procedures with an intervertebral body fusion device cleared by FDA for use with a bone void filler, Vitoss® can be mixed with saline, autogenous blood, bone marrow, and/or used on its own. 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® 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 osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of 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, pelvis, and spine, which includes intervertebral disc space and posterolateral fusion procedures). When used in intervertebral body fusion procedures with an intervertebral body fusion device cleared by FDA for use with a bone void filler, Vitoss® can be mixed with saline, autogenous blood, bone marrow, and/or used on its own. 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)	?

VB SPINE

510(k) Summary: Vitoss Bone Graft Substitute	
Submitter:	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person :	Name: Kristina Daoud Email: kristina.tawadros@vbspineco.com Secondary Contact: Name: Justin Eggleton Email: justin.eggleton@vbspineco.com
Date Prepared:	April 23, 2026
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 Foam Bone Graft Substitute Pack 6. Vitoss® Bioactive Foam Bone Graft Substitute 7. Vitoss® Foam Bone Graft Substitute 8. Vitos®s Bone Graft Substitute Filled Canister 9. Vitoss® Bone Graft Substitute
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

510(k) Summary: Vitoss Bone Graft Substitute	
Predicate Devices:	**Primary Predicate: K242280** 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 Foam Bone Graft Substitute Pack, Vitoss Bioactive Foam Bone Graft Substitute, Vitoss Foam Bone Graft Substitute, Vitoss Bone Graft Substitute Filled Canister, and Vitoss Bone Graft Substitute **Reference: K253147** FIBERGRAFT™ BG Putty GPS Bone Graft Substitute, FIBERGRAFT™ BG Putty Bone Graft Substitute, FIBERGRAFT™ AERIDYAN™ Matrix Bone Graft Substitute, and FIBERGRAFT™ BG Matrix Bone Graft Substitute
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® Bone Graft Substitute, 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 osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of 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, pelvis, and spine, which includes intervertebral disc space and posterolateral fusion procedures). When used in intervertebral body fusion procedures with an intervertebral body fusion device cleared by FDA for use with a bone void filler, Vitoss® can be mixed with saline, autogenous blood, bone marrow, and/or used on its own. 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.

510(k) Summary: Vitoss Bone Graft Substitute	
	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. **Vitoss® Bioactive Bone Graft Substitute, Vitoss® Bioactive Bone Graft Substitute Pack, Vitoss® Bioactive Foam Bone Graft Substitute** 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 intervertebral disc space and posterolateral fusion procedures) and may be combined with saline, autogenous blood, and/or bone marrow. These osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of traumatic injury to the bone. When used in intervertebral body fusion procedures with an intervertebral body fusion device cleared by FDA for use with a bone void filler, Vitoss® can be mixed with saline, autogenous blood, bone marrow, and/or used on its own. Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process. **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, intervertebral disc space, and posterolateral spine) and may be combined with saline, autogenous blood, and/or bone marrow. These osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of traumatic injury to the bone. When used in intervertebral body fusion procedures with an intervertebral body fusion device cleared by FDA for use with a bone void filler, Vitoss® can be mixed with saline, autogenous blood, bone marrow, and/or used on its own. Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.

510(k) Summary: Vitoss Bone Graft Substitute	
Summary of the Technological Characteristics	The subject Vitoss Bone Graft Substitute devices are substantially equivalent to the predicate devices. The subject devices have the same intended use, design, materials, operating principles, and performance specifications as their respective predicates. The proposed modification is to expand the indications statement within the subject Vitoss Bone Graft Substitute devices to include the pediatric population of ≥ 6 years old in addition to the posterolateral spine and use of previously cleared FDA cages which will not impact the safety and efficacy of the subject devices. There is no physical change to the products resulting from this IFU change and no new or significantly changed risks identified as a result. Therefore, the subject devices are substantially equivalent to their respective predicate devices.
Summary of the Performance Data	The expanded indications for use are supported by a clinical and performance testing rationale. No new performance testing was performed.
Conclusion	The subject devices have the same intended use with additions to the indications for use to align with the reference device. Per the clinical rationales detailed in this submission, the updated indications for use for the subject devices are substantially equivalent to their predicate and reference devices.