February 17, 2026

Biomendex Oy
℅ Susan Drapeau, PhD
Vice President
Dark Horse Consulting Regenerative Medicine
38 True Harbour Way
West Islip, New York 11795

Re: K253524
Trade/Device Name: Adaptos®Fuse Bone Graft
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: January 20, 2026
Received: January 20, 2026

Dear Dr. Drapeau:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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: 2026.02.17 11:19:47 -05'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
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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.	K253524

Please provide the device trade name(s).

Adaptos®Fuse Bone Graft

Please provide your Indications for Use below.

Adaptos®Fuse Bone Graft is intended for use in bony voids or gaps that are not intrinsic to the stability of the bony structures. These defects may be surgically created osseous defects or defects created from traumatic injury to the bone (i.e., posterolateral spine, intervertebral disc space, and pelvis). In interbody fusion procedures, Adaptos®Fuse Bone Graft must be used with interbody fusion devices FDA cleared for use with bone void filler. Adaptos®Fuse Bone Graft Granules must be mixed with autograft prior to use. Following placement in the bony void or gap, Adaptos®Fuse Bone Graft are resorbed and replaced with bone during the healing process.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Biomendex

510(k) Summary

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Date Prepared
11Oct2025

Device

Trade Name	Adaptos®Fuse Bone Graft
Common Name	Filler, Bone Void, Calcium Compound
Regulation	21 CFR 888.3045 Resorbable calcium salt bone void filler device
Classification	Class II
Product Code	MQV
Panel	Orthopedic

Predicates

Primary Predicate	NovaBone Putty – Bioactive Synthetic Bone Graft (K240404)
Additoinal Predicates	Synthes chronOS and chronOS Composite (K071046, K043045) NuVasive Attrax Putty (K203714) FIBERGRAFT® BG Putty (K222276)

Device Description
Adaptos®Fuse bone graft device is a bioactive bone void filler provided to the user as granules in open-bore syringes. The granules are made of poly(L-lactide-co-ε-caprolactone) (PLCL), tricalcium phosphate (TCP), and bioactive glass.

Indications for Use Statement

Adaptos®Fuse Bone Graft is intended for use in bony voids or gaps that are not intrinsic to the stability of the bony structures. These defects may be surgically created osseous defects or

defects created from traumatic injury to the bone (i.e., posterolateral spine, interbody fusion, and pelvis). In interbody fusion procedures, Adaptos®Fuse Bone Graft must be used with interbody fusion devices FDA cleared for use with bone void filler. Adaptos®Fuse Bone Graft Granules must be mixed with autograft prior to use.

Following placement in the bony void or gap, Adaptos®Fuse Bone Graft Granules are resorbed and replaced with bone during the healing process.

Substantial Equivalence

This submission demonstrates that Adaptos®Fuse Bone Graft Granules are substantially equivalent to NovaBone Putty – Bioactive Synthetic Bone Graft (K240404) and Synthes chronOS and chronOS Composite (K071046, K043045). The NovaBone Putty primary predicate and Synthes additional predicates have identical intended uses of resorbing and being replaced by new bone, consistent with 21 CFR 888.3046 and the description in FDA's Bone Void Filler Class II Special Controls. All predicates also identify the specific indications for posterolateral spine. Except for chronOS Composite, all predicates also include specific pelvis indications.

Adaptos®Fuse Bone Graft device is composed of poly(L-lactide-co-***ε***-caprolactone) (PLCL), tricalcium phosphate (TCP), and bioactive glass, whereas the primary predicate device, NovaBone Putty, is 70% Bioactive glass granules, 30% polyethylene glycol (PEG) and a glycerin binder. Additionally, Synthes chronOS and chronOS Composite contain ᵝ-tricalcium phosphate as does Adaptos®Fuse Bone Graft. All products are resorbable and can be mixed with autograft, whereas the indicated use of Adaptos®Fuse requires mixing with autograft and is therefore a narrower indication. The differences in product composition do not raise any difference questions of safety and effectiveness, and the testing supports that Adaptos®Fuse Bone Graft is as safe and as effective as NovaBone Putty Primary Predicate for the stated indications for use.

Performance

To support the relative safety and effectiveness, Biomendex provides device characterization, sterilization, shelf-life, endotoxin, elemental impurity test data, in vitro degradation, bioactivity, pyrogenicity, and biocompatibility test data to support substantial equivalence.
To support substantial equivalence with respect to performance, Biomendex provides an animal performance study in a posterolateral spine fusion model demonstrating that treatment with Adaptos®Fuse Bone Graft combined with autograft supported bridging bone and stable fusion as evidenced by manual palpation, high resolution x-ray, and histological analysis. The performance of Adaptos®Fuse Bone Graft was compared to the NovaBone Putty predicate in a rabbit posterolateral spine fusion model. At 12 weeks, Adaptos®Fuse Bone Graft had a higher fusion score than NovaBone Putty primary predicate and was equivalent to the autograft control.

Summary

The subject device and predicates have the same intended use, and the same specific indications for use. Any differences in technological characteristics between the subject device and predicate do not raise

different questions of safety and effectiveness and have been addressed with performance testing. Biomendex concludes that the device is substantially equivalent to the predicates.