October 26, 2023

Woven Orthopedic Technologies
Mr. Brandon Bendes
President and CEO
63 Center Street, #3a
Manchester, Connecticut 06040

Re: K233223
Trade/Device Name: Ogmend® Implant Enhancement System
Regulation Number: 21 CFR 888.3043
Regulation Name: Screw Sleeve Bone Fixation Device
Regulatory Class: Class II
Product Code: QVI
Dated: September 28, 2023
Received: September 28, 2023

Dear Mr. Bendes:

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,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

I011001

Device Name
Ogmend® Implant Enhancement System

Indications for Use *(Describe)*

The Ogmend® Implant Enhancement System is intended to augment pedicle screw fixation when a screw has lost purchase due to screw loosening, back-out, or breakage. The Ogmend® Implant Enhancement System is for use with rigid, thoracolumbar pedicle screw systems where a screw is inserted posteriorly, through the pedicle, and into the vertebral body. The Ogmend® Implant Enhancement System is for use in skeletally mature patients.

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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510K Summary

Manufacturer Identification

Woven Orthopedic Technologies
63 Center Street #3a, Manchester, CT 06040
Phone: 860-259-1260
Establishment Registration #3017505709
Contact Person: Brandon Bendes, President and CEO

Device Identification

Device Trade Name:	Ogmend® Implant Enhancement System
Device Common Name:	Screw Sleeve Bone Fixation Device
Classification Name:	Screw Sleeve Bone Fixation Device
Classification Number:	21 CFR 888.3043
Product Code:	QVI
Device Class:	Class II
Review Panel:	Orthopedic Devices
Date Summary Prepared:	September 28, 2023

Indications for Use

The Ogmend® Implant Enhancement System is intended to augment pedicle screw fixation when a screw has lost purchase due to screw loosening, back-out, or breakage. The Ogmend® Implant Enhancement System is for use with rigid, thoracolumbar pedicle screw systems where a screw is inserted posteriorly, through the pedicle, and into the vertebral body. The Ogmend® Implant Enhancement System is for use in skeletally mature patients.

Device Description

The Ogmend® Implant Enhancement System is a sterile, single-use device intended to provide supplemental fixation to restore stability when the screw-to-bone interface becomes mechanically compromised. The Ogmend® Implant Enhancement System includes a permanently implanted sleeve ("Ogmend® Implant") and an inserter ("Ogmend® Inserter").

The Ogmend® Implant Enhancement System is designed to use the principles of interference fit, surface area contact, and pressure distribution to secure a screw to bone and achieve stability at the screw-to-bone interface to allow for subsequent healing.

The Ogmend® Implant is manufactured from polyethylene terephthalate (PET) monofilament fibers.

The Ogmend® Implant is offered in two sizes:

- Medium: For use with screws ranging in diameter from 3.5mm – 6.5mm.
- Large: For use with screws ranging in diameter from 6.5mm – 10.5mm.

The Ogmend® Inserter is used to insert the Ogmend® Implant into the bone hole and can be used with both size Ogmend® Implants. The Ogmend® Inserter is a stainless-steel rod with beveled ends. It can be used to insert multiple sleeves within one operative procedure. It is provided sterile as a disposable, single-use device. The Inserter is compatible with sterilization by gamma radiation.

Primary Predicate Device

Ogmend® Implant Enhancement System (K223075).

Comparison of Technological Characteristics to Predicate

The subject Ogmend® Implant is identical to the primary predicate with respect to materials, design, principle of operation, sterilization method, inserter material, and shelf life as detailed below. The subject and predicate devices are also identical with respect to Intended Use and Indications for use.

Implant Material:	Polyethylene Terephthalate
Implant Design:	Braided PET Sleeve Implant
Principle or Operation:	Enhance Screw / Bone Interface
Sterilization Method:	Gamma Irradiation
Inserter Material:	Stainless Steel
Shelf Life:	36 Months

The distinguishing characteristics between the subject and predicate devices are detailed below:

Technological Characteristic	Medium Ogmend® Implant (K223075)	Large Ogmend® Implant (proposed)
Sleeve Diameter	6.5mm	8.5mm
Sleeve Length	100mm	150mm
Compatible Pedicle Screw Size Range	3.5mm – 6.5mm	6.5mm – 10.5mm

Performance Data

The bench tests listed below were performed to support the substantial equivalence of the subject device in addition to the bench tests were previously purposed on the primary predicate in K223075:

#	Performance Test
1	Screw Axial Pullout
2	Sleeve Insertion Force
3	Screw Insertion Torque
4	Screw Removal/Extraction Torque
5	Sleeve End Closure Strength
6	Device Breakage- Sleeve Durability

SUBSTANTIAL EQUIVALENT

The data presented in this submission demonstrates that the proposed Ogmend® Implant is substantially equivalent to the primary predicate with respect to intended use, technological characteristics, design, materials, principles of operation, and procedural steps, the pre-determined acceptance criteria, performance with respect to intended use.