February 27, 2023

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

Re: K223075
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: January 23, 2023
Received: January 24, 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 (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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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)*
K223075

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.

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510K SUMMARY

MANUFACTURER IDENTIFICATION

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

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:	February 15, 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 implant of the Ogmend® Implant System consists of sterile, single-use devices intended to provide supplemental fixation to restore stability when the screw-to-bone interface becomes mechanically compromised. The system includes a permanently implanted sleeve ("Ogmend® Implant" or "Ogmend®" or "Sleeve") and an inserter ("Ogmend® Inserter Instrument" or "Inserter") to insert the Ogmend® Implant.

When inserted into a prepared bone hole, the Ogmend® Implant 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 and provides a helically braided structure that is captured by a screw when the screw is advanced during placement. Ogmend® has an inner diameter of 6.5mm and an outer diameter of 7.5mm, and can be used with screws ranging in diameter from 3.5mm to 6.5mm. Ogmend® is supplied at a length of 100mm and is cut intra-operatively to the appropriate length.

The sole instrument used with the Ogmend® Implant System is the Inserter, which is used to insert the Sleeve into the hole. The Ogmend® Inserter is a stainless-steel rod with beveled ends. It can be used to insert multiple sleeves in a single 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 (DEN180065).

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject Ogmend® Implant is identical to the primary predicate in material, design, principle of operation, implant size, sterilization method, inserter material and shelf life as detailed below:

Implant Material:	Polyethylene Terephthalate
Implant Design:	Braided PET Sleeve Implant
Principle or Operation:	Enhance Screw / Bone Interface
Implant Size:	6.5mm
Sterilization Method:	Gamma Irradiation
Inserter Material:	Stainless Steel
Shelf Life:	36 Months

PERFORMANCE DATA

The following bench tests were performed to support the substantial equivalence of the subject device in addition to the bench testing that was previously performed on the primary predicate in DEN180065:

- Cyclic Wear Testing with Particulate Testing per ASTM F1877
- Dynamic Compression Bending Strength per ASTM F1717

Woven also performed an ovine spine study to further analyze the Ogmend® Implant according to biological and biomechanical metrics used to evaluate unique forces and movement placed on the screw-to-bone interface in the axial skeleton and in relation to commonly used spine fixation constructs (rods and screws).

In addition, Woven performed a prospective, multicenter, non-controlled, clinical trial to evaluate the safety and performance of the Ogmend® Implant Enhancement System in subjects for the proposed indication. The clinical data revealed no screw loosening or backouts in screws augmented with the Ogmend® device.

SUBSTANTIAL EQUIVALENCE

The clinical data, animal data, and bench testing data presented in this submission demonstrates that the proposed Ogmend® Implant Enhancement System is substantially equivalent to the primary predicate device with respect to intended use, technological characteristics, design, materials, principles of operation, and procedural steps.