May 1, 2020

Woven Orthopedic Technologies, LLC
% Glenn Stiegman
Senior Vice President, Clinical and Regulatory Affairs
Musculoskeletal Clinical Regulatory Affairs
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: DEN180065
Trade/Device Name: OGmend® Implant System
Regulation Number: 21 CFR 888.3043
Regulation Name: Screw sleeve bone fixation device
Regulatory Class: Class II
Product Code: QAC
Dated: December 11, 2018
Received: December 13, 2018

Dear Glenn Stiegman:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the OGmend® Implant System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The OGmend® Implant System is for the use with screws as part of a fracture fixation plate system in long bones in rescue scenarios where the screw has lost purchase due to screw loosening, back out, or breakage and the stability of the plate construct is at risk. The OGmend® Implant System is for use in skeletally mature patients.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov. FDA concludes that this device should be classified into Class II. This order, therefore, classifies the OGmend® Implant System, and substantially equivalent devices of this generic type, into Class II under the generic name Screw sleeve bone fixation device.

FDA identifies this generic type of device as:

> **Screw sleeve bone fixation device:** A screw sleeve bone fixation device is intended to be implanted in conjunction with a non-resorbable, metallic bone screw where the screw has lost purchase due to loosening, backout, or breakage. The device fits between the screw threads and surrounding bone,

and provides increased surface area to create an interference fit to restore stability of the implant construct.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On December 13, 2018, FDA received your De Novo requesting classification of the OGmend® Implant System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the OGmend® Implant System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the OGmend® Implant System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	**Mitigation Measures**
Loss of function / mechanical integrity resulting from: ▪ Device malposition ▪ Device breakage ▪ Damage to screw during insertion ▪ Deterioration due to aging ▪ Insufficient restoration of screw fixation	*In vivo* performance testing Non-clinical performance testing Shelf life testing Labeling
Revision	*In vivo* performance testing Non-clinical performance testing Labeling
Adverse tissue reaction	Biocompatibility evaluation *In vivo* performance testing Non-clinical performance testing Labeling
Infection	Sterilization validation Shelf life testing
Febrile response due to endotoxins	Pyrogenicity testing

In combination with the general controls of the FD&C Act, the Screw sleeve bone fixation device is subject to the following special controls:

Special Controls	
(1)	*In vivo* performance testing under anticipated conditions of use must demonstrate:
	(i) The device provides sufficient stability to allow for fracture healing; and
	(ii) A lack of adverse biologic response to the implant through histopathological and histomorphometric assessment.
(2)	Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must:
	(i) Assess the stability of the device in a rescue screw scenario;
	(ii) Demonstrate that the device can be inserted and removed without damage to the implant or associated hardware;
	(iii) Demonstrate the device can withstand dynamic loading without device failure; and
	(iv) Characterize wear particle generation.
(3)	The device must be demonstrated to be biocompatible.
(4)	The device must be demonstrated to be non-pyrogenic.
(5)	Performance data must demonstrate the sterility of the device.
(6)	Performance data must support the labeled shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the established shelf life.
(7)	Labeling must include:
	(i) A detailed summary of the device technical parameters;
	(ii) Information describing all materials of the device;
	(iii) Instructions for use, including device removal; and
	(iv) A shelf life.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Screw sleeve bone fixation device they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Jesse Muir, Ph.D. at 240-402-6679.

Sincerely,

Raquel A. Peat -S

CAPT Raquel Peat, Ph.D., M.P.H., USPHS
Director
OHT6: Office of Orthopedic Devices
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Center for Devices and Radiological Health