March 29, 2023

Bioretec Ltd.
% Jonathan Kahan
Partner
Hogan Lovell US LLP
555 13th Street Northwest
Washington, District of Columbia 20004

Re: DEN220030
Trade/Device Name: RemeOs™ Screw LAG Solid
Regulation Number: 21 CFR 888.3041
Regulation Name: Absorbable metallic bone fixation fastener
Regulatory Class: Class II
Product Code: QJD
Dated: May 4, 2022
Received: May 4, 2022

Dear Jonathan Kahan:

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 RemeOs™ Screw LAG Solid, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> RemeOs™ Screw LAG Solid is intended for the use in traumatic and orthopedic surgery for the fixation of bone fractures (osteosynthesis) and for the fixation after osteotomies, e.g., for the correction of deformities or malalignments. The absorbable implants serve as temporary fixation and stabilization by osteosynthesis of bone fractures and osteotomies until bony fusion has occurred.
>
> The RemeOs™ Screw LAG Solid is intended to be used for skeletally mature adults.
>
> The RemeOs™ Screw LAG Solid is indicated for the fixation of the medial malleolus.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the RemeOs™ Screw LAG Solid, and substantially equivalent devices of this generic type, into Class II under the generic name absorbable metallic bone fixation fastener.

FDA identifies this generic type of device as:

> **Absorbable metallic bone fixation fastener**. An absorbable metallic bone fixation fastener is an implant, such as a bone screw, pin, or Kirschner wire, composed of one or more absorbable metal or

metal alloys and intended to provide rigid bone fixation suitable for osteosynthesis. The device is designed to fully absorb after osteosynthesis is achieved.

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 May 4, 2022, FDA received your De Novo requesting classification of the RemeOs™ Screw LAG Solid. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the RemeOs™ Screw LAG Solid 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 RemeOs™ Screw LAG Solid 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:

Risks to Health	**Mitigation Measures**
Loss of bone fixation resulting from: • Premature device absorption and formation of absorption byproducts • Device breakage • Galvanic corrosion • Device aging	Clinical data Non-clinical performance testing Shelf-life testing Labeling
Adverse tissue reaction resulting from: • Device material • Device absorption and absorption by-products	Biocompatibility evaluation Labeling
Infection	Sterilization validation Shelf-life testing Pyrogenicity testing Labeling
Difficulties with revision surgery due to screw absorption	Clinical data Labeling

In combination with the general controls of the FD&C Act, the absorbable metallic bone fixation fastener is subject to the following special controls:

(1) Clinical data must demonstrate that the device performs as intended under the anticipated conditions of use. The absorption profile must be characterized to completion (full absorption). The difficulty of any revision surgeries must be documented.

(2) Non-clinical performance testing must demonstrate that the product performs as intended under anticipated conditions of use. Testing must:

(i) Evaluate the complete degradation profile of the device;
(ii) Evaluate the initial mechanical performance; and
(iii) Evaluate the mechanical performance as the device degrades.

(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 (i.e., degradation profile and mechanical performance) over the established shelf life.

(7) Labeling must include:

(i) Material composition;
(ii) Absorption byproducts;
(iii) A detailed summary of the product's technical parameters;
(iv) An expiration date/shelf-life;
(v) Instructions for revision surgery;
(vi) Time to complete absorption; and
(vii) A summary of clinical data with the device.

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

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.

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 absorbable metallic bone fixation fastener 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 Ryan Trombetta, Ph.D., at (301) 837-7355.

Sincerely,

Raquel A. Peat -S

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