December 19, 2017

IlluminOss Medical, Inc.
Fred Tobia
Vice President, RA/QA
993 Waterman Avenue
East Providence, RI 02914

Re: DEN160062
Trade/Device Name: IlluminOss Photodynamic Bone Stabilization System
Regulation Number: 21 CFR 888.3023
Regulation Name: In vivo cured intramedullary fixation rod
Regulatory Classification: Class II
Product Code: QAD
Dated: December 27, 2016
Received: December 28, 2016

Dear Mr. Tobia:

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 IlluminOss Photodynamic Bone Stabilization System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> IlluminOss Photodynamic Bone Stabilization System (PBSS) is indicated for skeletally mature patients in the treatment of impending and actual pathological fractures of the humerus, radius and ulna from metastatic bone disease.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the IlluminOss Photodynamic Bone Stabilization System, and substantially equivalent devices of this generic type, into Class II under the generic name in vivo cured intramedullary fixation rod.

FDA identifies this generic type of device as:

> **In vivo cured intramedullary fixation rod**. An in vivo cured intramedullary fixation rod is a prescription implanted device consisting of a balloon that is inserted into the medullary canal of long bones for the fixation of fractures. The balloon is infused with, and completely encapsulates, a liquid monomer that is exposed to a curing agent which polymerizes the monomer within the balloon creating a hardened rigid structure.

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 new 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, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. 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 classifying the device type.

On December 28, 2016, FDA received your De Novo requesting classification of the IlluminOss Photodynamic Bone Stabilization System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the IlluminOss Photodynamic Bone Stabilization 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 initial De Novo request and supplement, FDA has determined that, for the previously stated indications for use, the IlluminOss Photodynamic Bone Stabilization 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:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measures**
Adverse tissue reaction resulting from: • Balloon leakage • Device materials	Biocompatibility evaluation Labeling
Infection, including wound complications	Sterilization validation Reprocessing validation Shelf life testing Pyrogenicity testing Labeling
Bone fracture resulting from: • Device bending, cracking, or fracture • Device migration or instability, including initial inadequate fixation • Inability to properly deploy or remove device	Non-clinical performance testing Labeling
Soft tissue damage including transection or laceration of neural, vascular, or muscular structures.	Non-clinical performance testing Labeling
Pain and/or loss of function resulting from: • Balloon leakage	Non-clinical performance testing Labeling

• Device bending, cracking, or fracture • Device migration or instability, including initial inadequate fixation • Inability to properly deploy or remove device	
Revision	Non-clinical performance testing Labeling
Electric shock or interference with other electrical devices	Electrical safety testing Electromagnetic compatibility testing Labeling
Exothermic reaction leading to tissue injury	Non-clinical performance testing

In combination with the general controls of the FD&C Act, the in vivo cured intramedullary fixation rod is subject to the following special controls:

1. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
    a. Mechanical testing must be conducted on the final device to assess burst, abrasion, bending, and torsion in static and dynamic conditions.
    b. Mechanical testing must demonstrate the integrity of the balloon including testing for leaks, ruptures, and release of cured/uncured material.
    c. Performance testing must demonstrate that the device can be inserted and removed.
    d. Performance testing must demonstrate the ability, in the event of a leak, to remove the uncured material from its in vivo location.
    e. Performance testing must demonstrate the reliability and accuracy of the curing method used.
    f. Thermal safety testing must be conducted to evaluate the temperature rise during curing.

2. Electrical safety, electromagnetic compatibility (EMC) testing, and electromagnetic interference (EMI) testing must be conducted for all electrical components.

3. All patient-contacting components must be demonstrated to be biocompatible.

4. Performance data must demonstrate the sterility and pyrogenicity of patient contacting components of the device that are provided sterile.

5. Performance data must validate the reprocessing instructions for any reusable components or instruments.

6. Performance data must support the shelf life of the system by demonstrating continued sterility, package integrity, and system functionality over the established shelf life.

7. Technological characterization of the device must include materials, curing agents, and a description of the operating principles of the device, including the delivery system and devices which initiate the curing process.

8. Labeling must include the following:

a. A detailed summary of the device technical parameters.
b. Information describing all materials of the device.
c. Information describing how to perform the procedure and use the device, including the delivery system and devices which initiate the curing process, as well as how to remove the device and any uncured materials.
d. A shelf life.
e. Validated methods and instructions for reprocessing any reusable components or instruments.

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 in vivo cured intramedullary fixation rod 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Peter Allen at 301-796-6402.

Sincerely,

Angela C. Krueger -S

Angela C. Krueger
Deputy Director, Engineering and Science Review (Acting)
Office of Device Evaluation
Center for Devices and Radiological Health