December 13, 2018

IlluminOss Medical, Inc.
% Hollace Rhodes
Senior Director, Orthopedic Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisors, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K183145
Trade/Device Name: IlluminOss Photodynamic Bone Stabilization System
Regulation Number: 21 CFR 888.3023
Regulation Name: In Vivo Cured Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: QAD
Dated: November 12, 2018
Received: November 13, 2018

Dear Hollace Rhodes:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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

Sincerely,

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183145

Device Name

IlluminOss Photodynamic Bone Stabilization System ("IlluminOss PBSS")

Indications for Use *(Describe)*

IlluminOss Photodynamic Bone Stabilization System (PBSS) is indicated for use in skeletally mature patients in the treatment of traumatic, fragility, pathological, and impending pathological fractures of the humerus, radius, and ulna.

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.

510(k) Summary

Manufacturer: IlluminOss Medical, Inc.
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Prepared By: Musculoskeletal Clinical Regulatory Advisers, LLC
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Washington, DC 20001
Phone: 202.552.5800
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Date Prepared: November 12, 2018

Device Trade Name: IlluminOss Photodynamic Bone Stabilization System ("IlluminOss PBSS")

Classifications: 21 CFR 888.3023, In vivo cured intramedullary fixation rod

Class: Class II

Product Code: QAD

Predicate Device:
The modified IlluminOss Photodynamic Bone Stabilization System is substantially equivalent to the predicate IlluminOss Photodynamic Bone Stabilization System (K181228) with respect to indications, design, materials, function, and performance. The information summarized in the Design Control Activities Summary demonstrates that the modified IlluminOss Photodynamic Bone Stabilization System met the pre-determined acceptance criteria for the verification activities.

Indications for Use:
IlluminOss Photodynamic Bone Stabilization System (PBSS) is indicated for use in skeletally mature patients in the treatment of traumatic, fragility, pathological, and impending pathological fractures of the humerus, radius, and ulna.

The Indications for Use statement for the IlluminOss Photodynamic Bone Stabilization System device is identical to the predicate device.

Device Description:
The IlluminOss Photodynamic Bone Stabilization System provides an important treatment option in the fixation and stabilization of fractures through a minimally invasive procedure. The system uses a catheter to deploy an inflatable, noncompliant, thin wall PET balloon into the medullary canal of the bone across the fracture site. The balloon is infused using a standard 20cc syringe with a photodynamic (light cured) monomer that causes the balloon to slowly expand and fill the intramedullary canal of the fractured bone. Activation of the light system allows for visible spectrum light to be delivered through a radially emitting light pipe that is temporarily positioned into a central lumen of the catheter that runs the length of the balloon. With this design, the liquid monomer within the balloon is exposed to light along the entire length of the balloon during the curing process. The purpose of this Special 510(k) is to add smaller, intermediate, and larger sizes of the implant, an intermediate size of the Sheath/Dilator Set, and a smaller size of the Delivery Set.

Comparison of Technological Characteristics with Predicate Device:
The subject device and the IlluminOss PBSS predicate device are identical, with the exception of the addition of new small, intermediate, and large sizes of the implant and the auxiliary components to support these new sizes, specifically a new intermediate Sheath/Dilator Set and smaller reusable instruments and light pipe. These additional parts are not anticipated to introduce any new issues regarding device safety or effectiveness.

Performance Testing Summary:
Testing of the IlluminOss PBSS device includes:

1. Testing to demonstrate that the new device sizes could withstand the pressures necessary to complete the infusion process with the liquid monomer.
2. Testing to demonstrate that monomer sufficiently cures during the given cure time for the new implant sizes, providing sufficient mechanical strength
3. Mechanical testing to demonstrate the strength of the balloon catheter bond possess adequate tensile characteristics.
4. Mechanical testing to demonstrate the light pipe does not break upon removal and can sufficiently cure the monomer.

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to the predicate cited above with respect to indications, design, function, and performance.

Conclusion:

The IlluminOss PBSS device is substantially equivalent to the previously cleared device with respect to its indications for use, design, function, and performance.