IlluminOss Medical, Inc.
Robert Rabiner
Chief Technical Officer
993 Waterman Avenue
East Providence, Rhode Island 02914

June 25, 2020

Re: K200295
Trade/Device Name: IlluminOss 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: March 3, 2020
Received: March 4, 2020

Dear Robert Rabiner:

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,

For: Michael Owens, M.S., R.A.C.
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
/ K200295

Device Name
IlluminOss Photodynamic Bone Stabilization System

Indications for Use *(Describe)*
The IlluminOss Photodynamic Bone Stabilization System 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 IlluminOss Photodynamic Bone Stabilization System can also be used in conjunction with an FDA-cleared fracture fixation system to provide supplemental fixation in the humerus, radius, and ulna. It is also indicated for use in skeletally mature patients in the treatment of fractures of the pelvis, clavicle, metacarpals, metatarsals, and phalanges.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Manufacturer: IlluminOss Medical, Inc.
993 Waterman Avenue
East Providence, RI 02914
Phone: 401.714.0008

Contact: Mr. Robert Rabiner
Chief Technical Officer
IlluminOss Medical, Inc.
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Phone: 401.714.0008 x207
rrabiner@illuminoss.com

Prepared By: MCRA, LLC
1050 K Street, NW, Suite 1000
Washington, DC 20001
Phone: 202.552.5800

Date Prepared: May 27, 2020

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

Classification: 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 CurvaFix, Inc. Intramedullary Rod Screw System (K180050), Synthes (USA) Low Profile Reconstruction Plates (K042377), DePuy Orthopaedics, Inc. Rockwood Clavicle Pin (K103001), and Small Bone Innovations, Inc. MetaFLEX IM Nail System (K051605) with respect to intended use, indications for use, technological characteristics, and performance data. The previously cleared IlluminOss Photodynamic Bone Stabilization System (K183145) is considered a reference device, with identical device design, with the exception of the inclusion of new small and intermediate implant sizes. The information provided in this 510(k) demonstrates that the modified IlluminOss Photodynamic Bone Stabilization System is substantially equivalent to the identified predicate devices.

Indications for Use:
The IlluminOss Photodynamic Bone Stabilization System 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 IlluminOss Photodynamic Bone Stabilization System can also be used in conjunction with an FDA-cleared fracture fixation system to provide supplemental fixation in the humerus, radius, and ulna. It is also indicated for use in skeletally mature patients in the treatment of fractures of the pelvis, clavicle, metacarpals, metatarsals, and phalanges.

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 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 fiber 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 510(k) is to add smaller, and intermediate sizes of the implant and expand the indications for use to include the pelvis, clavicle, metacarpals, metatarsals, and phalanges.

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

1. Testing to demonstrate that the devices is of sufficient strength upon curing for the indications in the pelvis, clavicle, metacarpals, metatarsals, and phalanges.
2. Testing to demonstrate that the new device sizes could withstand the pressures necessary to complete the infusion process with the liquid monomer.
3. Testing to demonstrate that monomer sufficiently cures during the given cure time for the new implant sizes, providing sufficient mechanical strength

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

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