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

August 13, 2020

Re: K201961
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: July 14, 2020
Received: July 14, 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)*

K201961

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, ulna, clavicle, pelvis, fibula, metacarpals, metatarsals, and phalanges. The IlluminOss Photodynamic Bone Stabilization System can also be used in conjunction with FDA-cleared fracture fixation systems to provide supplemental fixation in these anatomic sites.

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.
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Phone: 401.714.0008

Contact: Mr. Robert Rabiner
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Prepared By: MCRA, LLC
1050 K Street, NW, Suite 1000
Washington, DC 20001
Phone: 202.552.5800

Date Prepared: July 14, 2020

Device Trade Name: IlluminOss Photodynamic Bone Stabilization System

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

Class: Class II

Product Code: QAD

Predicate Device:

The IlluminOss Photodynamic Bone Stabilization System is substantially equivalent to the Synthes Elastic Intramedullary Nail System (K081452) with respect to intended use, indications for use, technological characteristics, and performance data. The previously cleared IlluminOss Photodynamic Bone Stabilization System (K200295) serves as a reference device, with identical device design and technological characteristics, with the exception of expanding the indications to include use in the fibula. The information summarized in the Design Control Activities Summary demonstrates that the IlluminOss Photodynamic Bone Stabilization System met the pre-determined acceptance criteria for the verification activities.

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, ulna, clavicle, pelvis, fibula, metacarpals, metatarsals, and phalanges. The IlluminOss Photodynamic Bone Stabilization System can also be used in conjunction with FDA-cleared fracture fixation systems to provide supplemental fixation in these anatomic sites.

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 system is currently indicated for use in the humerus, radius, ulna, clavicle, metacarpal, metatarsal, phalanges, ulna, and anterior ring of the pelvic. The purpose of this Special 510(k) is to expand the indications for use to include the fibula.

Performance Testing Summary:
Testing of the IlluminOss PBSS device includes testing to demonstrate that the device is of sufficient strength upon curing for the fibular indications.

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to the predicates cited above with respect to indications, design, function, and performance. The technological characteristics of the subject device are identical to the previously cleared IlluminOss PBSS devices. Specifically, they are identical in design, size, materials, and chemical composition.