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

January 19, 2024

Re: K233436
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: December 20, 2023
Received: December 20, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2024.01.19 14:42:04 -05'00'

for: Farzana Sharmin, PhD
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K233436

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. The IlluminOss System may be used in the femur and tibia to provide supplemental fixation to an anatomically appropriate FDA-cleared fracture fixation system.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 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.
993 Waterman Avenue
East Providence, RI 02914
Phone: 401.714.0008 x207
rrabiner@illuminoss.com

**Date Prepared:** October 12, 2023

**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 (Rod, Fixation, Intramedullary And Accessories, In-Vivo Cured, Light Activated)

**Predicate Device:**
K202887 - IlluminOss Photodynamic Bone Stabilization System.

**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. The IlluminOss System may be used in the femur and tibia to provide supplemental fixation to an anatomically appropriate FDA-cleared fracture fixation system.

**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.

**Technological Similarities/Differences:**
The subject device introduces modifications to the light system and packaging configurations.

The modified light system includes a Lightsource with:

- A High Power (HP) LED light source to cure the implant; This replaces a metal halide bulb.
- Updated Light Fiber interface to attach the fiber directly to the LED Lightsource; This replaces an intermediary liquid lightguide that connected the Light Fiber to the Lightbox.
- A Radio Frequency Identification (RFID) system to set the light exposure time; This replaces a mechanically inserted timer key card.
- An LCD display screen as the main user interface; This replaces manual switches, foot pedal, and indicator lights for the use and activation of the system.

The modified packaging includes:

- A tray to hold multiple disposable system components in one pouch; This replaces individually packaged disposable system components packaged separately using the same packaging materials and sterilization method.
- A tray to hold multiple vials of the photodynamic (light cured) monomer in one pouch; This replaces individually packaged vials using the same packaging materials, sterilization method, and aseptic fill process.

**Performance Testing Summary:**
The technological characteristics of the subject device that differ from the predicate are supported by verification activities.

The modified light system is supported by:
- Functional Testing
- Software Testing
- Electrical Safety Testing
- Electromagnetic Compatibility Testing
- Human Factors and Usability Testing
- Shipping / Environmental Storage and Testing
- Implant Performance Testing

The modified packaging is supported by:
- Sterility Testing
- Packaging Performance Testing
- Shipping Testing

**Substantial Equivalence:**
The subject device and predicate device maintain the same intended use and differ only in technological characteristics. The light system and packaging configurations have been modified but perform similarly to the predicate while the *in vivo* cured implant is unchanged. The technological differences are all supported by verification activities and demonstrate that the device functions as intended. These differences in technological characteristics do not raise different questions of safety and effectiveness. Thus, it can be determined that the subject device is substantially equivalent to the predicate.