GLW, Inc.
℅ Nancy Lincé
President & CEO
Lincé Consulting, LLC
111 Deerwood Road, Suite 200
San Ramon, California 95483

February 19, 2021

Re: K201379
Trade/Device Name: Artemis Proximal Femoral Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: January 15, 2021
Received: January 19, 2021

Dear Nancy Lincé:

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
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)*

K201379

Device Name

Artemis Proximal Femoral Nail System

Indications for Use *(Describe)*

The Artemis Proximal Femoral Nail System is indicated for fixation of stable and unstable intertrochanteric fractures, including but not limited to nonunion, malunion and tumor resections.

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.

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510K SUMMARY

Date Prepared	January 15, 2021
Submitter	GLW, Inc. 300 Sylvan Avenue Englewood Cliff, NJ 07632 USA
Submitter Contact	Arundhati Radhakrishnan Quality Assurance Manager Phone: (201) 268-3281 Email: arundhati.radhakrishnan@glwmed.com
Correspondent Contact	Nancy Lincé Lincé Consulting, LLC President & CEO Phone: (650) 759-6186 Email: nlince@linceconsulting.com
Device Name	Artemis Proximal Femoral Nail System
Common Name	Rod, fixation, intramedullary and accessories Screw, fixation, bone
Class	Class II
Product Code	HSB HWC
Classification	21 CFR 888.3020: Intramedullary fixation rod 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Device Panel	Orthopedic
Primary Predicate	K043431 Gamma3 Trochanteric Nail
Reference Predicate	K173652 Piccolo Composite Nailing System

Device Description	The Artemis Proximal Femoral Nail System is an intramedullary fracture fixation system intended for temporary stabilization of bone segments or fragments in the proximal femur. The system includes single-use, sterile implants (Proximal Femoral Nail Kit Short, Locking Screw, and Lag Screw) as well as non-sterile, reusable, Class I and II surgical instruments. The nail and screws are made of titanium alloy Ti-6Al-4V. The titanium alloy nail is partially over-molded with carbon fiber reinforced polymer (CFR PEEK). The Artemis Nail is a cylindrical rod with a preassembled 4mm Set Screw, available in one size with a distal diameter of 11mm, a proximal diameter of 16.4mm, and a length of 180mm. The Nail is designed with holes, at the proximal and distal sections, for the insertion of a Lag Screw and Locking Screw, respectively. The Lag Screw has a diameter of 11mm and is available in various lengths ranging from 70mm to 130mm. The Locking Screw has a diameter of 5mm and is available in various lengths ranging from 25mm to 110mm.
Indications for Use	The Artemis Proximal Femoral Nail System is indicated for fixation of stable and unstable intertrochanteric fractures, including but not limited to nonunion, malunion and tumor resections.
Performance Data	The Artemis Proximal Femoral Nail System successfully underwent mechanical testing in accordance with ISO 7206-4, ASTM F1264, and ASTM F543. Performance characteristics for the Artemis Proximal Femoral Nail System components included static and dynamic bending of construct, and screw torque to failure and are comparable to those of predicate devices, thus demonstrating that the device is substantial equivalent to the predicate.
Clinical Performance Data	Clinical data was not needed for this device.
Substantial Equivalence	Device comparisons demonstrate that the Artemis Proximal Femoral Nail System is substantially equivalent to the predicate device in terms of intended use, indications for use, technological characteristics and operating principles. The primary difference between the predicate and subject devices is the nail material; the predicate device is constructed from titanium alloy and the subject device is constructed from titanium alloy and partially over-molded CFR PEEK. The reference device is included to address the material difference.
Conclusion	The information included in the 510(k), which included comparison testing to the predicate, demonstrates that any minor differences between the subject and predicate devices do not raise new issues of safety or effectiveness when the device is used as intended.