GLW, Inc.
% Cheryl Wagoner
Principal Consultant
Wagoner Consulting LLC
5215 Crosswinds Drive
Wilmington, North Carolina 28409

October 27, 2022

Re: K221489
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: September 29, 2022
Received: September 30, 2022

Dear Cheryl Wagoner:

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 Victoria Lilling, M.D.
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)*
K221489

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.

Additionally, the long nail kit is indicated for the fixation of subtrochanteric fractures and shaft fracture extending distally to a point approximately 10 cm proximal to the intercondylar notch.

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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510(k) Summary

Submitter	GLW Medical Innovation
Address	300 Sylvan Ave Englewood Cliff, NJ 07632
Telephone	917-0794-2583

Contact Person	Arundhati Radhakrishnan
Address	300 Sylvan Ave Englewood Cliff, NJ 07632
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Date Prepared	October 24, 2022

Trade Name	Artemis Proximal Femoral Nail System
Common Name	Rod, fixation, intramedullary and accessories Screw, fixation, bone
Panel Code	Orthopaedics/87
Classification	21 CFR 888.3020 Intramedullary fixation rod 21 CFR 888.3040 Smooth or threaded metallic bone
Class	Class II
Product Code	HSB: Rod, fixation, intramedullary and accessories HWC: Screw, fixation, bone

Predicate Device (primary)	**510(k) #**	**Manufacturer**
Artemis Proximal Femoral Nail System	K201379	GLW Medical Innovation
Predicate Device (additional)	**510(k) #**	**Manufacturer**
Gamma 3 TNail System	K043431	Stryker
Apollo Ankle Plating System	K213005	GLW Medical Innovation
CREED Cannulated Screws	K200291	GLW Medical Innovation
Zimmer Biomet Affixus Hip Fracture Nail	K183162	Zimmer Biomet

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, Proximal Femoral Nail Kit Long, Locking Screw, Lag Screw, and optional anti-rotational locking pins) 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 Nails are available in short or long lengths from 180mm to 440mm and are cylindrical rods with preassembled Set Screws. 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. Optional Anti-rotational Locking Pins are also available to aid in rotational stability.

Indications and Intended 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. Additionally, the long nail kit is indicated for the fixation of subtrochanteric fractures and shaft fracture extending distally to a point approximately 10 cm proximal to the intercondylar notch.

Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the Subject device, Artemis Proximal Femoral Nail System is substantially equivalent to the primary predicate Artemis Proximal Femoral Nail System (K201379). The subject and predicate (K201379) are identical in intended use, material, and manufacturing processes. The difference in the indications for use use statements includes the addition of the subject long nail kit. Additionally, the proposed changes to technological characteristics do not raise different questions of safety and effectiveness as compared to the predicate device.

	Comparison
Materials	**Identical**
Sterilization method	**Identical**
Diameter	**Identical**
Length	**Short-unchanged** **Subject Long-additional sizes**
Angle	**Identical**
Locking options	**Short-unchanged** **Subject Long-identical + additional anti rotational locking screws**
Lag screw/locking screw	**Identical**
Method of fixation	**Identical**
Mechanics of action	**Identical**

Performance Data	The Artemis Proximal Femoral Nail System successfully underwent mechanical testing in accordance with ASTM F1264 and ASTM F543. Performance testing of the Artemis Proximal Femoral Nail System components also included static and dynamic bending of the construct based on ISO 7206-4. No clinical data was necessary.

Conclusion	Based on the indications for use, technological characteristics, materials, and comparison to the predicate devices, the subject Artemis Proximal Femoral Nail System has been shown to be substantially equivalent to a legally marketed predicate device.