March 11, 2022

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

Re: K213005
Trade/Device Name: Apollo Ankle Fracture Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: February 8, 2022
Received: February 9, 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: Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma 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)*

K213005

Device Name
Apollo Ankle Fracture Plating System

Indications for Use *(Describe)*

Apollo™ Ankle Fracture Plating System is intended for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula such as:

- Lateral Malleolar Fractures
- Syndesmosis Injuries
- Medial Malleolar Fractures
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Posterior Malleolar Fractures
- Distal Anterior Tibia Fractures
- Vertical Shear Fractures of the Medial Malleolus
- Pilon Fractures
- Distal Tibia Shaft Fractures
- Distal Fibula Shaft Fractures
- Distal Tibia Periarticular Fractures
- Medial Malleolar Avulsion Fractures
- Lateral Malleolar Avulsion Fractures

Apollo Locking Screws are intended for use with Apollo's Plating Systems.

Apollo non-Locking Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

Apollo washer is intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/ load over a large area when used for fracture fixation of bone fragments.

Apollo 1/3 tubular plates are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

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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Traditional 510(k) Premarket Notification
Apollo™ Ankle Fracture Plating System

510(k) Summary
(as required by 21 CFR 807.92)

Date Prepared	September 17, 2021
Manufacturer	GLW, Inc.
Address	300 Sylvan Ave Englewood Cliff, NJ 07632
Telephone	917-794-2583
Contact Person	Arundhati Radhakrishnan
Address	300 Sylvan Ave Englewood Cliff, NJ 07632
Telephone	201-268-3281
Email	Arundhati.radhakrishnan@glwmed.com

Trade Name	Apollo™ Ankle Fracture Plating System
Common Name	Plate, Fixation, Bone Screw, Fixation, Bone
Panel Code	Orthopaedics/87
Classification Name	Single/multiple component metallic bone fixation appliances and accessories. Smooth Or Threaded Metallic Bone Fixation Fastener
Class	Class II
Regulation Number	21 CFR 888.3030 21CFR 888.3040
Product Code	HRS HWC

Name of Primary Predicate Device	**510(k) #**	**Manufacturer**
Ortholoc 3Di Ankle Fracture System	K163044	Wright Medical
Name of Reference Device(s)	**510(k) #**	**Manufacturer**
In2Bones Colink View	K193543	In2Bones
CREED™ Cannulated Screws	K200291	GLW, Inc

Description	Apollo™ Ankle Fracture Plating System consists of implantable components that will be include an array of Titanium alloy Ti-6AL-4V ELI (ASTM F3001) / PEEK plates and locking and non-locking screws. The screws are offered in configurations that include a range of Titanium alloy Ti-6AL-4V ELI (ASTM F136) screws. A variety of instrumentation is offered as part of the kit to

	facilitate delivery of the implants. The implantable devices are provided sterile via Gamma irradiation.

Indications and Intended Use	Apollo™ Ankle Fracture Plating System is intended for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula such as: • Lateral Malleolar Fractures • Syndesmosis Injuries • Medial Malleolar Fractures • Bi-Malleolar Fractures • Tri-Malleolar Fractures • Posterior Malleolar Fractures • Distal Anterior Tibia Fractures • Vertical Shear Fractures of the Medial Malleolus • Pilon Fractures • Distal Tibia Shaft Fractures • Distal Fibula Shaft Fractures • Distal Tibia Periarticular Fractures • Medial Malleolar Avulsion Fractures • Lateral Malleolar Avulsion Fractures Apollo Locking Screws are intended for use with Apollo's Plating Systems. Apollo non-Locking Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device. Apollo washer is intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/load over a large area when used for fracture fixation of bone fragments. Apollo 1/3 tubular plates are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.
Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the Subject device is substantially equivalent to the primary predicate Wright Medical Ortholoc 3Di Ankle Fracture System (K1603044). The Subject device is substantially equivalent to the predicate devices in intended use, indications for use, materials, technological characteristics, and labeling.

	The Subject device is similar in size and form as the predicate(s). The Subject and predicate both contain Ti-alloy screws.

Performance Data	The plate components were tested via ASTM F382 and were shown to be at least equivalent to the predicate devices. Torsional strength, driving torque and axial pullout testing (per ASTM F543 and FDA Guidance for Bone Screws and Washers, December 2020) confirmed that the Subject device screws performed as intended and are at least equivalent to the predicate devices. Static 3-point bending, and dynamic 3-point bending per ASTM F1264 further confirmed the performance and substantial equivalence of the Subject device screws.

Conclusion	Based on the intended use, indications for use, technological characteristics, materials, and comparison to predicate/ reference devices, the Subject device has been shown to be substantially equivalent to legally marketed predicate devices.