September 14, 2020

GLW Medical Innovation
Elijah Wreh
Regulatory Consultant
300 Sylvan Avenue
Englewood Cliffs, New Jersey 07632

Re: K200343
Trade/Device Name: FusionFrame Ring Lock System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTT
Dated: August 5, 2020
Received: August 7, 2020

Dear Elijah Wreh:

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,

Ting Song, Ph.D., R.A.C.
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)*
K200343

Device Name
FusionFrame™ Ring Lock System

Indications for Use *(Describe)*
The FusionFrame Ring Lock System is indicated for:

- Stabilization of fractures and osteotomies;
- Bone deformity correction of lower extremities;
- Arthrodesis of the rear foot, mid foot and ankle joint; and
- Limb Lengthening in pediatric and adult patients.

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 Information per 21 CFR 807.92(a)(1)

SPONSOR:	GLW Medical Innovation 300 Sylvan Ave Englewood Cliffs, NJ 07632
PRIMARY CONTACT:	Arundhati Radhakrishnan Quality Assurance Manager
SECONDARY CONTACT:	Elijah & Elisha, LLC Regulatory Consultant
MANUFACTURER:	GLW Medical Innovation 300 Sylvan Ave Englewood Cliffs, NJ 07632 Tel: (877) 287-0795
DATE PREPARED per 21 CFR 807.92(a)(1):	13 September 2020

Device Information per 21 CFR 807.92(a)(2)

NAME OF SUBJECT DEVICE:	FusionFrame™ Ring Lock System

COMMON/USUAL NAME:	External Fixator

CLASSIFICATION NAME:	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories (21 CFR 888.3030)

REGULATORY CLASS:	2

PRODUCT CODE:	KTT - Single/Multiple Component Metallic Bone Fixation Appliances and Accessories

PREDICATE DEVICES:	Primary Predicate: FUSION MEDICAL RING LOCK SYSTEM (K100857) Secondary Predicates: SALVATION External Fixation System (K180832) ILIZAROV EXTERNAL FIXATION SYSTEM (K962808)

Device Description per 21 CFR 808.92(a)(4)

This submission is a line extension to the FusionFrame™ Ring Lock System product line to include fixation pins, pin fixation bolts, pin fixation cubes, threaded sockets, conical washer couples, T-wrench and adapters, hinges, telescoping struts and 5/8 rings to improve the configuration options that the FusionFrame™ Ring Lock System can provide and to be competitively comparable to other circular external fixation predicate devices.

The FusionFrame™ Ring Lock System is an updated version of previously existing circular fixators that is specifically designed for the treatment of pathologies including:

- Stabilization of Fractures and Osteotomies.
- Bone deformity corrections of lower extremities.
- Arthrodesis of:
    - Rear Foot
    - Mid Foot
    - Ankle Joint
- Adult and pediatric limb lengthening

The Fusion Frame was developed to specifically address the extensive requirements of orthopedic surgeons and foot and ankle specialists. Its components have been designed to ensure overall construct stability, versatility, ease of application, functionality and time saving efficiency. Briefly described, the FusionFrame™ provides a weight bearing scaffold that in most cases allows patients to remain mobile throughout the course of treatment.

The numerous variety of constructs afforded by the FusionFrame™ provides a systematic platform for ensuring stability, re-aligning bones, applying compressive forces or controlling the distraction of bone fragments over a period of time. The FusionFrame™ consists of externally mounted Rings and ancillary components that are interconnected with threaded rods and/or telescoping struts. The construct is attached to the bone with a combination of percutaneously applied tensioned Wires and/or Half-Pins. Telescoping struts with compression/distraction nuts may be attached to the frame to systematically control the gaps between bone fragments and distance between Rings to manage a variety of pathologies. Threaded rods or struts may be used to reduce and compress fracture zones, lengthen limbs and even correct deformities.

Indications for Use per FORM FDA 3881

The FusionFrame Ring Lock System is indicated for:

- Stabilization of fractures and osteotomies;
- Bone deformity correction of lower extremities;
- Arthrodesis of the rear foot, mid foot and ankle joint; and
- Limb Lengthening in pediatric and adult patients.

Indications for Use Characteristics Comparison

Both the subject and predicate devices share the same Indications for Use and Intended use.

Technological Characteristics Comparison with the predicate device per 21 CFR 807.92(a)(6)

The technological characteristics comparison demonstrates that the subject device is substantially equivalent in intended use, design, materials, and operational principles to the previously cleared predicate devices.

Basis of Substantial Equivalence per 21 CFR 807.100(b)(2)(ii)(A)

The substantial equivalence of the subject device was determined as per the FDA guidance document, "***The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]***" and the technological characteristics which include materials, design, operational principles and other device features, as defined in section 513(i)(1)(B) of the FD&C Act and 21 CFR 807.100(b)(2)(ii)(A).

The subject device is a modification to the previously cleared FUSION MEDICAL RING LOCK SYSTEM (K100857) and contains components and features that are similar to the predicate device.

The performance testing, device comparison, and dimensional analysis demonstrate that the subject device and features are the same or substantially equivalent to the predicate devices identified throughout this 510(k) submission. The data generated from the subject device design verification test reports support a finding of substantial equivalence regarding the device comparison, dimensional analysis, device specifications, and design characteristics.

Performance Data

Non-Clinical Test per 21 CFR 807.92(b)(1)

Non-clinical laboratory testing was performed on the worst-case subject device to determine substantial equivalence. The following testing was performed with reference to ASTM F1541-17 Standard Specification and Test Methods for External Skeletal Fixation Devices:

- *Static Torsion Test and Cantilever bend test on Half pins*
- *Static Axial Compression Testing on Struts*

Design Verification testing demonstrated that the subject device is substantially equivalent to the currently marketed predicate devices.

Animal Study

Animal testing was not required for this submission.

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The subject device has the same intended use and technological characteristics as the predicate devices. The design verification data support a finding of substantial equivalence of the subject device and demonstrate that the subject device will perform as intended in the specified use conditions.