Genesis Fracture Care, Inc.
% Christine Scifert
Managing Partner
MRC-X, LLC
6075 Poplar Ave Suite 500
Memphis, Tennessee 38119

October 23, 2017

Re: K171293
Trade/Device Name: G3™ Active Plate® Miniature 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: September 18, 2017
Received: September 21, 2017

Dear Christine Scifert:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K171293

Device Name

G3™ Active Plate® Miniature System

Indications for Use *(Describe)*

The G3™ Active Plate® Miniature System is intended for fracture fixation in patients 18 years of age and older requiring stabilization of mal-unions, non-unions, osteotomies and repair of closed and open fractures in small bones. The system is indicated for the fixation of small bone fractures including, but not limited to, fractures of the hand, foot, wrist and ankle.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

G3™ Active Plate® Miniature System

September 18, 2017

Company: Genesis Fracture Care, Inc.
13568 SE 97th Ave
Suite 202
Clackamas, OR 97015
503-528-4048
503-413-5216 (fax)

Primary Contact: Christine Scifert

Company Contact: Michael Bottlang

Trade Name: G3™ Active Plate® Miniature System

Common Name: Plate, Fixation, Bone
Screw, Fixation, Bone

Classification: II

Regulation Number: 888.3030 - Single/multiple component metallic bone fixation appliances and accessories
888.3040 - Smooth or threaded metallic bone fixation fastener

Panel: 87-Orthopedic

Product Code(s): HRS, HWC

Device Description: The G3™ Active Plate® Miniature System is a straight plate and locking screw system intended to be used for fracture fixation of the hand and foot. All implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-ELI), medical grade cobalt chrome alloy (Co-28Cr-6Mo) and silicone elastomer in the subject device.

The plate has 8 holes. The plates incorporate link elements, which are constrained within the plate and embedded in an elastomer sheath that is bonded to both the plate and the link element. Once locking screws are inserted, the active elements allow for independent controlled axial translation of the screws. The screws are 1.5 mm diameter and come in lengths ranging from 8 mm to 24 mm.

Indications for Use: The G3™ Active Plate® Miniature System is intended for fracture fixation in patients 18 years of age and older requiring stabilization of mal-unions, non-unions, osteotomies and repair of closed and open fractures in small bones. The system is indicated for the fixation of small bone fractures including, but not limited to, fractures of the hand, foot, wrist and ankle.

Substantial Equivalence: The subject components were demonstrated to be substantially equivalent to the following systems previously cleared by the FDA:

Primary Predicate

- Hand Innovations (Zimmer Biomet Inc.) - Mini Fragment Plates (K061748)

Additional Predicates

- DePuy Synthes - Variable Angle Locking Hand System (K141527)
- DePuy Synthes - Small Bone Locking Plating System (K083364)
- Small Bone Innovations - SBI K-Wires (K051605)
- Wright Medical - WMT Implantable K-wires (K132895)

Reference Devices

- Genesis Fracture Care (Zimmer Biomet Inc.) - G3™ Active Plate® Large Fragment System (K152242)

The subject G3™ Active Plate® Miniature System has demonstrated to be substantially equivalent to the predicates as the products are similar in indications, materials, geometry, and active feature.

	Subject of Present 510(k): **G3™ Active Plate® Miniature Plate**	**Predicate Devices**
Intended Use/ Indications for Use	The G3™ Active Plate® Miniature System is intended for fracture fixation in patients 18 years of age and older requiring stabilization of mal-unions, non-unions, osteotomies and repair of closed and open fractures in small bones. The system is indicated for the fixation of small bone fractures	Inclusive

	including, but not limited to, fractures of the hand, foot, wrist and ankle.	
Materials	Titanium Alloy (Plate) Silicone – NuSil (Plate) Cobalt Chrome (Screws)	Identical
Geometry and Dimensions	Plates: 8 holes Length: 25 mm Locking Screws: Diameter: 1.5mm Lengths: 8 mm – 24 mm	Inclusive

Performance Testing: Mechanical testing including axial, torsional and shear stiffness and four-point bend per ASTM F382-08 was performed on the subject G3™ Active Plate® Miniature System and the results show the subject plates to be substantially equivalent to the predicate devices. Engineering analysis was used to compare the torsional strength, axial pullout strength and insertion/removal torque of the subject screws to the predicates.

Conclusion

Based on the test results and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predict devices.