



November 24, 2015

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Genesis Fracture Care, Incorporated
% Ms. Christine Scifert
Managing Partner
Memphis Regulatory Consulting, LLC
3416 Roxee Run
Bartlett, Tennessee 38133

Re: K152242

Trade/Device Name: G3™ Active Plate® Large Fragment 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: October 7, 2015

Received: October 9, 2015

Dear Ms. 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

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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 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 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 yours,

Lori A. Wiggins -S

for

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

K152242

Device Name

G3™ Active Plate® Large Fragment System

Indications for Use (Describe)

The G3™ Active Plate® Large Fragment system is intended for use in adult and pediatric (subpopulation: transitional adolescent B (18 years to <21 years) cases requiring stabilizations of mal-unions, non-unions, and osteotomies of long bones, as well as repair of closed, open and periprosthetic fractures. The system is indicated for the fixation of long bone fractures including but not limited to fractures of the humerus, tibia, and femur, particularly in osteopenic bone.

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® Large Fragment System******November 23, 2015***

Company: Genesis Fracture Care, Inc.
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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® Large Fragment 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 subject G3™ Active Plate® Large Fragment System is a straight plate and locking screw system comprised of a variety of sizes to accommodate various patient anatomy and pathology. The plates and screws are intended to be used for long bone fracture fixation. All implantable components are manufactured from stainless steel (316L) and medical grade titanium alloy (Ti-6Al-4V-ELI). The screws are 5.0 mm diameter and come in lengths ranging from 14 to 145 mm. The plates range in size from 6 holes to 14 holes. The plates incorporate sliding elements, which are constrained within the plate and embedded in an elastomer sheath made from silicone that is bonded to the sliding element. Once locking screws are inserted, the active elements allow for independent controlled axial translation of the screws. All instruments are made from stainless steel.

Indications for Use: The G3™ Active Plate® Large Fragment system is intended for use in adult and pediatric (subpopulation: transitional adolescent B (18 years to <21 years) cases requiring stabilizations of mal-unions, non-unions, and osteotomies of long bones, as well as repair of closed, open and periprosthetic fractures. The system is indicated for the fixation of long bone fractures including but not limited to fractures of the humerus, tibia, and femur, particularly in osteopenic bone.

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

- Primary Predicate
 - G3™ Active Plate Large Fragment System (K142938, S.E. 11/26/2014 & K150649, S.E. 04/30/2015)
- Predicates:
 - Synthes 4.5mm LCP Reconstruction Plates (K051986, S.E. 09/08/2005)
 - Zimmer Periarticular Locking Plate System (K040593; S.E. 04/12/2004 & K042598, S.E. 10/29/2004)
- Reference Devices:
 - Smith & Nephew Ilizarov External Fixation System (K962808, S.E. 8/19/1996)
 - Orthofix Dynamic Axial Fixation System (K955848, S.E. 5/20/1996)

In addition to being substantially equivalent in terms of intended use, geometry, and active feature the subject G3™ Active Plate® Large Fragment System has also demonstrated to be substantially equivalent in terms of construct stiffness performance when compared to the previously cleared reference devices K955848 and K962808. The subject G3™ Locking Screws have also demonstrated to be substantially equivalent to those in the previously cleared Zimmer Periarticular Locking Plate System (K042598; S.E. 10/29/2004) in terms of performance. Finally, the G3™ Active Plate® Large Fragment System has demonstrated to be substantially equivalent to the G3™ Active Plate Fragment System (K142938; S.E. 11/26/2014) in both fatigue and construct fatigue testing.

	Subject of Present 510(k):	Predicate Devices
	G3™ Active Plate™	
Intended Use/ Indications for Use	The G3™ Active Plate® Large Fragment system is intended for use in adult and pediatric (subpopulation: transitional adolescent B (18 years to <21 years) cases requiring stabilizations of mal-unions, non-unions, and osteotomies of long bones, as well as repair of closed, open and periprosthetic fractures. The system is indicated for	Inclusive

	the fixation of long bone fractures including but not limited to fractures of the humerus, tibia, and femur, particularly in osteopenic bone.	
Primary Material	Titanium Alloy or Stainless Steel	Identical
Geometry and Dimensions	<u>Plates:</u> 6 - 14 holes; Lengths: 145 mm - 305 mm <u>Locking Screws:</u> Diameter: 5.0 mm Lengths: 14 mm - 145 mm	<u>Plates:</u> 2 - 24 holes; Lengths: 56 mm - 444 mm <u>Locking Screws:</u> Diameter: 4.0mm – 6.5 mm Lengths: 10 mm - 130 mm

Performance Testing: Mechanical testing, including stiffness, fatigue, pullout, torsion, torque, construct fatigue and wear have been performed per ASTM F543 and ASTM F382 on the subject G3™ Active Plate® Large Fragment System, as well as the G3™ locking screws used within the system, have shown them to be substantially equivalent to the predicate plate and screw systems. In addition, a biocompatibility evaluation was conducted to demonstrate substantial equivalence to the predicate device.