



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

April 22, 2016

Re: K160633

Trade/Device Name: G3™ Active Plate® Small 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: March 4, 2016

Received: March 7, 2016

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 Parts 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 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" (21CFR 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,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K160633

Device Name

G3™ Active Plate® Small Fragment System

Indications for Use (Describe)

The G3™ Active Plate® Small 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 and open fractures. The system is indicated for the fixation of long bone fractures including but not limited to fractures of the humerus, tibia, fibula, and radius.

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® Small Fragment System*

*March 11, 2016*

**Company:** Genesis Fracture Care, Inc.  
13568 SE 97<sup>th</sup> 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® Small 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 G3™ Active Plate® Small Fragment System is a straight plate and locking screw system comprised of a variety of sizes to accommodate various patient anatomy and pathology. The plate and screw are intended to be used for fracture fixation. All implantable components are manufactured from medical grade stainless steel and silicone elastomer the same as the subject device. The screws are 3.5 mm diameter and come in lengths ranging from 10 to 90 mm. The plates range in size from 6 hole to 18 hole. The plates incorporate sliding elements, which are constrained within the plate and embedded in an elastomer sheath 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 and open fractures. The system is indicated for the fixation of long bone fractures including but not limited to fractures of the humerus, tibia, fibula, and radius.

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

- Zimmer® Universal Locking System (K060710; S.E.4/26/2006)
- Zimmer® MotionLoc™ Screw for Periarticular Locking Plate System (K130810; S.E. 9/19/2013)
- Smith & Nephew Locking Bone Plate System (K033669; S.E. 12/10/2003 and K083032, S.E. 01/07/2009)
- Genesis Fracture Care G3™ Active Plate® Large Fragment System (K152242; S.E. 11/24/2015)
- Genesis Fracture Care G3™ Active Plate® Large Fragment System (K142938; S.E. 11/26/2014)

In addition to being substantially equivalent in terms of intended use, materials, geometry, and active feature, the subject G3™ Active Plate® Small Fragment System has also demonstrated to be substantially equivalent in terms of construct stiffness performance when compared to the previously cleared titanium G3™ Active Plate Large Fragment System (K152242, S.E. 11/24/2015). The subject G3™ Locking Screws have also demonstrated to be substantially equivalent to those in the previously cleared Zimmer Universal Locking System (K060710; S.E. 04/26/2006) in terms of performance. Finally, the G3™ Active Plate® Small Fragment System has demonstrated to be substantially equivalent to the 3.5mm Zimmer® MotionLoc™ Universal Plating System (Stainless Steel – K060710; S.E. 04/26/2006) in fatigue and Smith & Nephew PERI-LOC Bone Plating and Screw System (K033669, S.E. 12/10/2003 and K083032, S.E. 01/07/2009) and 3.5mm Zimmer® MotionLoc™ Universal Plating System (Stainless Steel – K060710; S.E. 04/26/2006) in construct fatigue testing.

	<b>Subject of Present 510(k):</b>  <b>G3™ Active Plate™</b>	<b>Predicate Devices</b>
<b>Intended Use/ Indications for Use</b>	The G3™ Active Plate® Small 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 and open fractures. The system is indicated for the fixation of long bone fractures including but not	Inclusive

	limited to fractures of the humerus, tibia, fibula, and radius.	
<b>Primary Material</b>	Stainless Steel	Identical
<b>Geometry and Dimensions</b>	<u>Plates:</u> 6 - 18 holes; Lengths: 145 mm - 305 mm  <u>Locking Screws:</u> Diameter: 3.5 mm  Lengths: 10 mm - 90 mm	Inclusive

**Performance Testing:** Mechanical testing, including stiffness, fatigue, pullout, torsion, torque, and construct fatigue have been performed per ASTM F543 and ASTM F382 on the subject G3™ Active Plate® Small 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.