DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Graham Medical Technologies, L.L.C. dba GraMedica
% Linda Braddon, Ph.D.
Secure BioMed Evaluations
7828 Hickory Flat Highway, Suite 120
Woodstock, Georgia 30188

October 3, 2014

Re: K142534
Trade/Device Name: HyProCure II (HYP II and HYP IIs)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 5, 2014
Received: September 9, 2014

Dear Dr. Linda Braddon:

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 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

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)*

K142534

Device Name

HyProCure II (HYP II and HYP IIs)

Indications for Use *(Describe)*

HyProCure II (HYP II and HYP IIs) is an implant stabilization device used in the treatment of hyperpronating instability of the hindfoot. The implant is designed to stabilize the talus to prevent excessive anterior, and/or medial, and/or plantarflexion of the talus, while allowing normal talotarsal joint motion.

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

In accordance with 21 CFR 807.87 (h) and 21 CRF 807.92, the 510(k) summary for the GraMedica HyProCure II is provided below.

Date Summary Prepared	September 5, 2014
Manufacturer / Distributor / Sponsor	GraMedica 16137 Leone Drive Macomb, MI 48042 586-677-9600 (office) 586-677-9615 (fax) ARecchia@GraMedica.com (email)
510(k) Contact	Secure BioMed Evaluations Linda Braddon, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 (direct) 855-MED-DEV1 (office) LGB@SecureBME.com
Trade Name	HyProCure II (HYP II and HYP IIs)
Common Name	Sinus Tarsi Implant
Code –Classification	**HWC** 21 CFR 888.3040 : Class II
Predicate Devices	K042030 HyProCure Subtalar Implant System
Device Description	The HyProCure II is an implant which stabilizes the talus on the tarsal mechanism. The system consists of an implant designed to be inserted into the sinus tarsi and corresponding instrumentation to facilitate insertion.
Intended Use	HyProCure II (HYP II and HYP IIs) is an implant stabilization device used in the treatment of hyperpronating instability of the hindfoot. The implant is designed to stabilize the talus to prevent excessive anterior, and/or medial, and/or plantarflexion of the talus, while allowing normal talotarsal joint motion.
Technological Characteristics	HyProCure II is of similar sizes, material choices and configurations as compared to the predicate.
Non-Clinical Performance Testing Conclusion	Non-clinical data was not necessary to show substantial equivalence
Substantial Equivalence Summary (Conclusion)	Based on the indications for use, technological characteristics, and comparison to predicate devices, the HyProCure II system has been shown to be substantially equivalent to legally marketed predicate devices, and safe and effective for its intended use.