



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 16 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Michael E. Graham, DPM  
Chief Executive Officer  
Graham Medical Technologies, LLC  
45700 Schoenherr Road  
Shelby Township, Michigan 48315

Re: K042030

Trade/Device Name: HyProCure Subtalar Implant System  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: HWC  
Dated: July 23, 2004  
Received: July 28, 2004

Dear Dr. Graham:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

Page 2 -- Michael E. Graham, DPM

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
for Celia M. Witten, Ph.D., M.D.

Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Indications for Use:

510(k) Number: K042030

Device Name: HYPROCURE SUBTALAR IMPLANT SYSTEM

*The HyProCure Subtalar Implant is indicated for use in the treatment of the hyperpronated foot by stabilization of the subtalar joint. The implant is designed to block anterior, and/or medial, and/or plantarflexion of the talus, while allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.*

**This device is prescription use only.**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K042030

Page 1 of 1