JAN 14 1999

510(k) Summary

GOTFRIED PC.C.P

PERCUTANEOUS COMPRESSION PLATING OF HIP FRACTURES

510(k) Number K983814

Submitter's Name:

EFRATGO LTD.
HI TECH BIO-SURGICAL
10 Ben Gurion St.
Kyriat Bialik 27000, Israel
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Contact Person:

Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 Thirteenth St, NW
Washington, DC 20004
Tel: (202) 637-5794
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Trade Name:

GOTFRIED PC.C.P (PERCUTANEOUS COMPRESSION PLATING OF HIP FRACTURES)

Classification Name:

Proximal Femoral Fixation Implant Device

Classification:

The FDA has classified these devices in Class II (product code 87 JDO). Proximal femoral fixation implant devices are reviewed by the Orthopedic and Rehabilitation Devices Branch.

Intended Use:

The GOTFRIED PC.C.P is intended to treat stable and unstable intertrochanteric, pertrochanteric, and base of neck hip fractures.

Device Description:

The GOTFRIED PC.C.P system is a plate and screw system, made of stainless steel, which utilizes dynamic femoral neck screws. The plate accepts two neck screws (length ranging from 90 mm to 140 mm) having barrel (sleeve) diameter of 9.3 mm and shaft diameter of 6.4 mm, and three 4.5 mm cortical screws (length ranging from 31 to 43 mm).

Substantial Equivalence:

The GOTFRIED PC.C.P is substantially equivalent to the Synthes Proximal Femoral Nail (PFN), cleared under K970097, and the Zimmer Versa-Fx Femoral Fixation System, cleared under K954555, in terms of intended use, material and design. Moreover, based on biomechanical test results, the biomechanical characteristic of the GOTFRIED PC.C.P is at least equivalent to other compression hip screw systems in terms of bending and torsional stiffness and ultimate loads to failure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 1999

Mr. Jonathan S. Kahan
Hogan & Hartson, L.L.P.
Representing Efratgo, Limited Hi Tech Bio-Surgical
555 13th Street, NW
Washington, DC 20004-1109

Re: K983814
Trade Name: Gotfried Percutaneous
Compression Plating System
Regulatory Class: II
Product Code: JDO
Dated: October 28, 1998
Received: October 28, 1998

Dear Mr. Kahan:

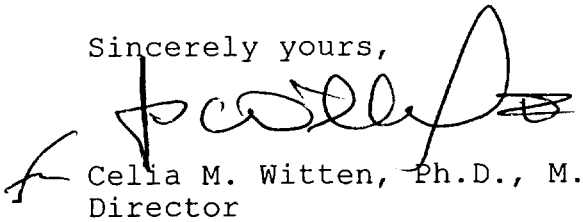
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K983814

Device Name: **GOTFRIED PC.C.P**
(PERCUTANEOUS COMPRESSION PLATING OF HIP FRACTURES)

Indications for Use:

The GOTFRIED PC.C.P is intended to treat stable and unstable intertrochanteric, pertrochanteric, and base of neck hip fractures.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over the Counter Use _____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983814