K083648

p. 1/1

510(k) Summary

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

MAY 14 2009

1.	***Submitter Address:***	Efratgo Ltd. Hi Tech Bio-Surgical 49 Derech Acco Ave. Kiryat Motzkin Israel 26736
	Phone:	972-4-870-6628
	Contact Person:	Yechiel Gotfried, MD
	Date:	December 4, 2008
2.	***Device & Classification Name:***	Gotfried PH (Physiological Hip) Nail Device: Rod, Fixation, Intramedullary, and Accessories
3.	***Predicate Devices:***	K040656- Smith & Nephew Intramedullary Hip Screw K043431- Stryker Gamma3 Locking Nail K043233- Gotfried Physiological Hip (PH) Nail
4.	***Description:***	The Gotfried PH (Physiological Hip) Nail is an intramedullary nail which utilizes two proximal dynamic femoral neck screws and up to two distal locking bolts.
5.	***Intended Use:***	The Gotfried PH (Physiological Hip) Nail is intended for fractured bone stabilization, fixation, and management of trochanteric (intertrochanteric and pertrochanteric), subtrochanteric, subcapital (intra capsular), and base of neck fractures of the proximal femur.
6.	***Comparison of Technological Characteristics:***	In terms of technology, the Gotfried PH (Physiological Hip) Nail is substantially equivalent to its predicate devices. It is constructed of stainless steel and incorporates the same orthopedic design principles and components as its predicate devices. Its dimensions and the majority of tolerances are within the range that has been previously determined to be substantially equivalent by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2009

Efratgo Ltd. Hi Tech Bio-Surgical
% MedicSense
Mr. George J. Hattub
Senior Staff Consultant
291 Hillside Avenue
Somerset, Massachusetts 02726

Re: K083648
Trade/Device Name: The Gotfried PH (Physiological Hip) Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: April 28, 2009
Received: May 1, 2009

Dear Mr. Hattub:

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.

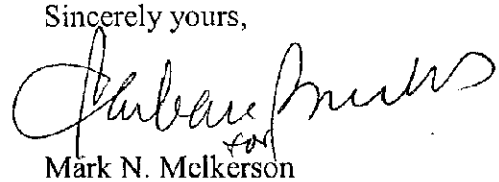
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

K083648 p. 1/1

Indications for Use

510(k) Number (if known):

Device Name: The Gotfried PH (Physiological Hip) Nail

Indications For Use: The Gotfried PH (Physiological Hip) Nail is intended for fractured bone stabilization, fixation, and management of trochanteric (intertrochanteric and pertrochanteric), subtrochanteric, subcapital (intra capsular), and base of neck fractures of the proximal femur.

Prescription Use __X_____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083648