K111001 (1/2)

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E) 510(k) Summary

Submitted by	Peter Ogrodnik Managing Director Intelligent Orthopaedics Limited Building 103 Campbell Road Stoke on Trent Staffordshire ST4 4DE United Kingdom
Date	25th March 2011
	Contact person: Peter Ogrodnik
Proprietary Name	Sterile STΦRM®® Operating Kit
Common Name	External Fixation Systems
Classification / Reference	Class II – 888.3040 Smooth or Threaded Bone Fixation fasteners
Product Code & Panel	HTY and HWC / Orthopedic

Device Description

The STΦRM™ Operating Kit consists of two Kirschner wires with collets (diameter 2mm; one length 280mm, the other length 400mm), two self threading 4.5mm bone screws and a 3.2mm single use drill bit.

Intended Use

The STΦRM™ Operating Kit is used in conjunction with the STΦRM™ in the reductic and fixation of fractures of the lower leg or distal femur

Technological characteristics

The STΦRM™ Operating Kit components are made from stainless steel and are presented sterile.

Substantial Equivalence

The components of the Sterile STΦRM™ Operating Kit are substantially equivalent to K061607 STΦRM™ Operating Kit

Equivalency is based on similarities in intended use, materials and design to the predicate devices and the mechanical performance demonstrating substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Intelligent Orthopaedics Limited
% Staffordshire University
Mr. Peter Ogrodnik
Managing Director
Business Village, Leek Road
Stoke On Trent, Staffordshire
United Kingdom ST4 2AR

MAY 17 2011

Re: K111001
Trade/Device Name: STΦRM™ Operating Kit
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HTY
Dated: March 25, 2011
Received: April 22, 2011

Dear Mr. Ogrodnik:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111001 (1/1)

510(k) Number (if known): K111001

Device Name: ___STΦRM™ Operating Kit_____

Indications for Use:

The STΦRM™ Operating Kit is used in conjunction with the STΦRM™ in the reduction and fixation of fractures of the lower leg or distal femur.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

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

510(k) Number K111001