K061607 Pg 1 of 2

PO Box 2681
Stoke on Trent
ST4 9BE

T: +44 (0) 17 82 84 78 40
F: +44 (0) 17 82 84 60 46
www.intelligent-orthopaedics.co.uk

JUL 18 2006

E) 510(k) Summary or 510(k) Statement

Submitted by	Peter OGrodnik Managing Director Intelligent Orthopaedics Limited Building 103 Campbell Road Stoke on Trent Staffordshire ST4 4DE United Kingdom
Date	26th May 2006
Contact person	Julio Gonzalez BSN medical Inc 5285 Carnegie Blvd Charlotte NC
Proprietary Name	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 reduction and fixation of fractures of the lower leg or distal femur

Technological characteristics

The STΦRM®® Operating Kit components are made from stainless and are presented non-sterile for sterilisation by autoclave.

Substantial Equivalence

The components of the STΦRM™ Operating Kit are substantially equivalent to K960385 - Sterile Kirschner Wires and Steimann Pins, DePuy; K983121 - Non-Sterile Kirschner wires and Steinmann Pins, Syntec-Taichung Medical Instruments co Ltd and K043185- Synthes 3.5mm Cortex Screws, Synthes.

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
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2006

Intelligent Orthopaedics Limited
% BSN medical Ltd.
Mr. Neil McLachlan
Global RA Manager
Brierfield Mill
Brierfield, Nelson
Lanchashire BB9 5NJ

Re: K061607
Trade/Device Name: STΦRM™ Operating Kit
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY, HWC
Dated: May 31, 2006
Received: June 9, 2006

Dear Mr. McLachlan:

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.
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 (240) 276-0120. 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 (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 General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

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)

Barbara Buchman for

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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510(k) Number K061607