K070724 Page 1/2

PO Box 2661
Stoke on Trent
ST4 9BE

T: +44 (0) 17 82 54 78 40
F: +44 (0) 17 82 54 60 46
www.intelligent-orthopaedics.co.uk

MAY 16 2007

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	8 February 2007
Contact person	Julio Gonzalez BSN medical Inc 5285 Carnegie Blvd Charlotte NC
Proprietary Name	iφs External Fixation Device
Common Name	External Fixation Systems
Classification / Reference	Class II – 888.3030 Single / Multiple Component Metallic Bone Fixation Appliances and Accessories
Product Code & Panel	KTT / Orthopedic

Device Description

The iφs fixator construct comprises of a main body which incorporates a central portion with larger ends with three 10mm diameter holes in each to accommodate bone screws. It is available in two lengths - 70 mm and 110mm. A screw sleeve fits into each hole and the bone screw is passed through each sleeve and into the bone fragment through the skin. The bone screw is secured to the fixator using a grub screw (passing through the sleeve) and tightening onto the screw directly. The iφs fixator is a single use device.

Intended Use

The iφs fixator is intended for use in the treatment of bone conditions including fracture fixation and other bone conditions which are amenable to treatment by the use of external fixation

Technological characteristics

The components of the iϕs fixator are made from titanium alloy and stainless steel

Substantial Equivalence

The components of the iϕs fixator are substantially equivalent to K031919 – EBI XFIX DFS system.

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

Intelligent Orthopaedics Ltd.
% Mr. Neil McLachlan
BSN Medical Ltd.
Brierfield Mill
Brierfield, Nelson
Lancashire BB9 5NJ
United Kingdom

MAY 16 2007

Re: K070724
Trade/Device Name: IΦS External Fixator
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Product Code: KTT
Dated: April 30, 2007
Received: May 4, 2007

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): K070724

Device Name: ___ iφs External Fixator

Indications for Use:

The IΦS fixator is intended for use in the treatment of bone conditions including fracture fixation and other bone conditions which are amenable to treatment by the use of external fixation.

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 Bruemmer

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

D-2

510(k) Number K070724