MAY 28 2003

K031219

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SUMMARY OF SAFETY AND EFFECTIVENESS
Orthofix Inc.
ISKD Internal Limb Lengthening System

I. GENERAL INFORMATION

Classification Name:	Intramedullary fixation rod
Common Name:	Internal Limb Lengthener
Device Trade Name:	"ISKD": (Intramedullary Skeletal Kinetic Distractor)
Classification Code(s):	21 CFR Parts 888.3020
Submitter's Name & Address:	Orthofix Inc. 1720 Bray Central Drive McKinney, TX 75069 (469) 742-2561
Establishment Registration No:	2183449
Contact Person:	Mary Biggers, RAC 469-742-2561
Summary Preparation Date:	April 7, 2003

II. PREDICATE DEVICE

The Orthofix Inc. ISKD System 10.7mm internal limb lengthener is substantially equivalent in design, function and intended use to the Orthofix Inc. 12.5mm internal limb lengthener. The Orthofix ISKD 12.5mm internal limb lengthener, manufactured by Orthofix Inc. of McKinney, Texas, was originally cleared by FDA under K010322 on May 2, 2001.

III. DEVICE DESCRIPTION

The ISKD System is an intramedullary limb lengthening system that provides gradual, controlled osteogenic distraction of the tibia and femur. The ISKD System consists of the telescoping internal limb lengthening device, titanium locking screws, instrumentation and an external hand-held Monitor. As the patient performs rotational oscillations of the affected limb during normal ambulation, the ISKD distracts as the distal section of the implant gradually telescopes out of the proximal section. The distraction is controlled by a one-way clutch mechanism and a threaded rod. A small magnet sealed within the ISKD implant rotates simultaneously as the implant distracts. The hand-held external Monitor is similar to an

electronic compass and communicates with the magnet by detecting and tracking changes in the magnet poles. The external Monitor enables both patients and physicians to monitor the daily limb lengthening progress. The addition of the 10.7mm lengthener will provide surgeons with a device option for patients requiring a smaller diameter implant.

IV. INDICATIONS FOR USE

The ISKD System intended for limb lengthening of the femur and tibia.

V. BIOMECHANICAL TESTING

In order to demonstrate that the 10.7 ISKD Limb Lengthener has the mechanical properties necessary to perform its intended use, and that the ISKD Internal Limb Lengthener performs as well as or better than the predicate device, Orthofix has conducted mechanical and functional testing of the 10.7mm lengthener in accordance with ASTM 1264, Standard Specification and Test Methods for Intramedullary Fixation Devices. These tests consist of 4-point bend, fatigue and torsion testing. The testing was successfully completed demonstrating the 10.7mm lengthener performs as well as the 12.5mm ISKD lengthener.

VI. BIOCOMPATIBILITY

The ISKD Internal Limb Lengthening device and locking screws are made from titanium alloy, Ti6A14V ELI conforming to ASTM F136.

X. STERILIZATION

The ISKD Internal Limb Lengthener is sterilized by exposure to ethylene oxide gas. The Instrumentation and devices provided non-sterile must be sterilized prior to use using the parameters identified below:

ISKD Non-Sterile Devices/Instruments	
Method	Steam Sterilization
Cycle	**Pre-Vacuum**
Temperature	132° - 135° C [270° - 275°F]
Exposure Time	Minimum of 10 minutes
Sterility Assurance Level (SAL)	10^{-6}
Sterility Validation Method	ANSI/AAMI ST46-1993– Prevacuum Steal Sterilization of Medical Devices

X. SUBSTANTIAL EQUIVALENCE

The 10.7mm ISKD Tibial Internal Limb Lengthener is claimed to be substantially equivalent in design and function to the 12.5mm ISKD Tibial Internal Limb Lengthener. The 12.5mm ISKD received 510(k) clearance under K010322 on May 2, 2001.

Features	ISKD 10.7mm	ISKD 12.5MM
Intended Use	"Limb lengthening of the tibia and femur"	"Limb lengthening of the tibia and femur"
MATERIAL	Ti6A14V ELI	Ti6A14V ELI
DESIGN FEATURES	Intramedullary nail	Intramedullary nail
	Telescoping sections	Telescoping sections
	One way clutch design	One way clutch design
METHOD OF FIXATION	4.0 mm & 4.8mm diameter locking screws	4.8mm diameter locking screws
NUMBER OF FIXATION POINTS	2 proximal/2 distal	2 proximal/2 distal
DESIGN OF ENDS	Blunt	Blunt
CROSS SECTIONAL SHAPE	Circular	Circular
RATE OF LENGTHENING	Physician to determine rate. Dependent upon patient activity level; .75-1.25 mm/day	Physician to determine rate. Dependent upon patient activity level; .75-1.25 mm/day
CONTROL OF LENGTHENING	Patient's activity level, i.e., rotational oscillations of the limb	Patient's activity level, i.e., rotational oscillations of the limb
MONITORING OF DISTRACTION	External hand held monitor; X-rays for confirmation	External hand held monitor; X-rays for confirmation
SAFETY FEATURES	Automatic stop when predetermined length is achieved. And one-way clutch design	Automatic stop when predetermined length is achieved. And one-way clutch design
SIZE RANGES (LENGTHS)	10.5 (215-350mm)	12.5 (255-435mm)
INVASIVE COMPONENTS	Intramedullary limb lengthener, Locking screws	Intramedullary limb lengthener Locking screws

XI. CONCLUSION

Based upon the results of biomechanical testing the ISKD 10.7mm internal limb lengthener has the mechanical properties to perform its intended use of limb lengthening of the tibia and is considered to be substantially equivalent to the predicate device in design, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2003

Ms. Mary Biggers, RAC
Manager, Regulatory Affairs
Orthofix, Inc.
1720 Bray Central Drive
McKinney, Texas 75069

Re: K031219
Trade/Device Name: ISKD (Intramedullary Skeletal Kinetic Distractor) System
Regulation Numbers: 21 CFR 888.3020
Regulation Names: Intramedullary fixation rod
Regulatory Class: II
Product Codes: HSB
Dated: April 11, 2003
Received: April 17, 2003

Dear Ms. Biggers:

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.

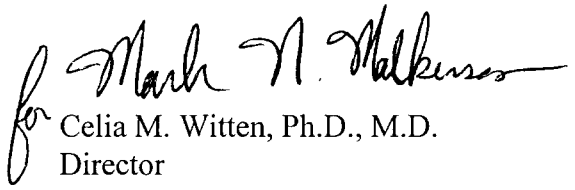
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K031219

Device Name: **"ISKD"**
Intramedullary Skeletal Kinetic Distractor

Indications for Use:

The ISKD is indicated for limb lengthening of the tibia and femur.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: _____
(Per 21 CFR 801.109)

Or

Over-The-Counter___
(Optional Format 1-2-96)

for Mark N Milhous

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

510(k) Number K031219