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K010322

SUMMARY OF SAFETY AND EFFECTIVENESS
ORTHODYNE ISKD SYSTEM

I. GENERAL INFORMATION

Classification Names:	Intramedullary fixation rod & Smooth or threaded metallic bone fixation fastener
Common Name:	Internal Limb Lengthener
Device Trade Name:	"ISKD": (Intramedullary Skeletal Kinetic Distractor)
Classification Code(s):	21 CFR Parts 888.3020 and 888.3040
Submitter's Name & Address:	Orthodyne Inc. 1118 So. Orange Avenue, Suite 204 Orlando, FL 32804 (407)316-8098
Establishment Registration No:	pending
Contact Person:	Carl Knobloch
Summary Preparation Date:	January 17, 2001

II. PREDICATE DEVICE

The Orthodyne ISKD System is substantially equivalent to two commercially available devices. The Orthodyne ISKD System is substantially equivalent in design and function to the Grosse and Kempf Locking Nail System manufactured by Howmedica Corp. of Rutherford, New Jersey. The Gross Kempf (i.e., GK Nail) device was originally cleared by FDA under K813371 on March 1, 1982, and most recently under K983358 on November 18, 1998. The Orthodyne ISKD System is substantially equivalent in intended use to the Orthofix Dynamic Axial Fixation System cleared by FDA under 510(k) K955848 on March 20, 1996

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. Titanium locking screws (2 proximal and 2 distal) secure the device in place in the intramedullary canal.

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 ISKD Internal 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, Orthodyne has conducted mechanical and functional testing of the ISKD System.

Static 4-point bend testing, torsional testing, nail fatigue testing, 3-point bend testing of the locking screw and functional testing was performed on the ISKD System. In general, the ISKD internal limb lengthener was more rigid in 4-point bending than the predicate nails. Also, the ISKD internal limb lengthener was stiffer in torsion than the predicate nails. In all nail fatigue testing, all nails ultimately completed the necessary one million cycles. In the 3-point bend testing of the locking screws, the statistical analysis showed the ISKD screws significantly greater in yield strength, ultimate strength and fatigue life than a commercially available bone screw. The stiffness was slightly higher but was not statistically significant. All samples passed the functional testing of the clutches, magnet and interface with the locking screws.

VI. ANIMAL TESTING

A 10mm ISKD Internal Limb Lengthener was implanted in the left femur of a 20-month old female sheep. The start length of the ISKD was 15cm. After the desired distraction, the device was designed to lock both linearly and torsionally to function as a static intramedullary (IM) nail until bone regenerate formation was complete.

The sheep was allowed to immediately bear full weight on the implant without the use of any external device constraining movement. Radiographs of the femur were taken 3 times a week for the first 3 weeks. By design, the threaded rod within the ISKD is easily identifiable on radiograph. The pitch of the threads is 1mm per rotation of the rod. (Note: the external monitoring device was not available at the time of this study). Thus, the length of number of threads seen between the clutches on each consecutive radiograph. ISKD distraction was determined within 0.5 mm by counting the increase in the number of threads seen between the clutches on each consecutive radiograph.

During the first 10 days following surgery, the animal walked with a slight limp, gradually increasing the use of the limb with the implant. By the second week, no noticeable preferential treatment was given to any limb, and the animal walked normally. Although the sheep's limb was not manipulated or constrained during this time, the ISKD distracted at a relatively consistent 1.3mm each day. After 27mm of distraction, on Day 21, this prototype implant prematurely stopped lengthening. (The cause was addressed in a redesign.) After the ISKD stopped lengthening, the sheep continued to function normally without giving preferential treatment to any limb.

The usual physiologic formation of regenerate bone tissue continued normally. Callus formation was visible on radiograph at 19 days. An anterior bridge of callus was evident at 35 days. At no time did the sheep show signs of infection or unusual pain. On Day 40 the sheep was transported to a sheep farm and allowed to roam a 70-acre field with other sheep. Full circumferential osteogenic callus formation was verified at 78 days. Radiographic evaluation of both the undisturbed bone and the lengthened bone showed comparable remodeling of the femoral diaphysis. On day 106 the ISKD implant was surgically removed from the sheep. A radiograph of the harvested femur shows complete cortical bone formation. The periosteum was stripped from the femur and the bone was bisected down its longitudinal axis with a band saw. The regenerate bone is comparable to that of the undisturbed callus. In summary, the results of this animal study indicate that the ISKD lengthening device performed as intended and successfully lengthened the femur in an ovine model without untoward effects.

VII. BIOCOMPATIBILITY

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

VIII. CLINICAL TESTING

Orthodyne has clinical experience with 19 patients implanted with an ISKD Internal Limb Lengthener. Upon IRB approval, nine patients participated in a pilot study followed a 10 patient feasibility study.

The nine patients participating in the pilot study were considered "compassionate use" as these patients presented with complicated histories, numerous risk factors including unresolved poly-trauma, severe soft tissue defect, severe contractures, poor bone quality, previous and recurring infections, multiple illnesses, etc. These patients required limb lengthening of the femur or the tibia ranging from from 31-105mm. And in most cases, the ISKD was a last stage option as these patient's deformities were so extreme and/or previous lengthening procedures had failed.

Despite their complicated histories, eight of the nine patients were able to achieve the limb length they needed. One patient received 75mm out of the 105mm of length needed, but was not able to lengthen further due to the severe soft tissue contractures resulting from the pre-existing soft tissue deficit.) Certain design improvements were made to the ISKD system based upon this clinical experience.

Ten patients are enrolled to date into the feasibility study. The feasibility study patients presented with fewer complications and risk factors than those in the pilot study. Of the 10 patients, seven were males and three were females; age at surgery ranged from 18-63 with a mean age of 40.8 years. The cause of limb discrepancy was trauma for nine patients and post-polio infection for one patient. Eleven lengthening procedures were performed with these 10 patients (one patient required 2 procedures to reach his goal length). The discrepancy range was 30-120mm, with a mean discrepancy of 57.6mm. The goal length range was 30-80mm with a mean of 48.1mm. The distraction period range (implant to end of distraction) was 22-169 days, with a mean of 83 days. The length attained was 23-80mm, with a mean range of 45.0mm. The distraction rate range was 0.40-1.79mm/day, with a mean range of 0.78mm/day. Of these 10, eight patients achieved the length needed.

Two of the patients were noncompliant – one exceeded the recommended level of daily physical activity and one failed to meet the recommended level of daily physical activity. Six patients achieved complete healing (4/4 with intact cortices); and four patients achieved partial healing (3/4 intact cortices) as of the last completed radiographic follow-up.

Of the four patients who achieve partial healing, two patients were lost to follow-up, and one patient had a second ISKD implanted and healed afterwards. The fourth patient is still being followed and has since been noted as healed by the physician. Of those who completely healed, the consolidation period range was 219-505 days.

Four patients experienced a total of eight adverse events. Two events (a loose screw and a broken screw) were device related. These events occurred after distraction was complete and did not affect outcome. Six events were determined to be unrelated to the device (two related to the lengthening procedure, one due to a pre-existing condition, one due to surgical error, one as a complication of surgery and one non-compliance).

Though the feasibility study patients presented with fewer complications and risk factors, it was determined that patients presenting with severe soft tissue defects and/or contractures should be excluded as this complicates limb lengthening process and can prevent proper functioning of the ISKD.

IX. STERILIZATION

ISKD Intramedullary Lengthening device	
Method	Gamma Radiation
Radiation Dose	25 Mrad
Sterility Assurance Level	10^{-6}
Sterility Validation Method	ANSI/AAMI ST32-1991; Method I
Packaging	PETG tray with double Tyvek lid
Pyrogenicity	Not labeled pyrogen free

ISKD Instrument Set	
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

ISKD is claimed to be substantially equivalent in design and function to

FEATURES	ISKD	GROSSE & KEMPF INTRAMEDULLARY LOCKING NAIL	ORTHOFIX DYNAMIC AXIAL FIXATION SYSTEM
INTENDED USE	"Limb lengthening of the tibia and femur"	"Temporary stabilization of various types of fractures, osteotomies, malunions and nonunions of the femur and tibia. Other types of procedures include reconstrunction, bone lengthening/shortening, prophylactic nailing of impending fractures and fusions.	Intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation and other bone conditions amendable to treatment by use of the external fixation modality.
MATERIAL	Ti6A14V ELI	316 LVM Stainless Steel	316 LVM stainless steel bone pins
DESIGN FEATURES	Intramedullary nail	Intramedullary nail	Unilateral external fixator
	Telescoping sections	NA	Telescoping sections
	One way clutch design	NA	Both compression and distraction
METHOD OF FIXATION	4.0 mm diameter smooth shaft Locking screws (proximal and distal)	Tibial: 4.6mm threaded Locking Screws (proximal and distal)Femoral: 6.28mm threaded Locking Screws Proximal and distal)	Bone pins
NUMBER OF FIXATION POINTS	2 proximal/2 distal	Tibial - 2 proximal/2 distal Femoral - 1 proximal/2 distal	2-3 proximal/ 2-3 distal
DESIGN OF ENDS	Blunt	Blunt	NA
LONGITUDINAL CURVATURE	Tibial Device - 15°±1° bend; femoral – none	Tibial- 17.5°; femoral – none	None
CROSS SECTIONAL SHAPE	Circular	Tibial: Slotted Cloverleaf Femoral: Partially slotted Cloverleaf	NA

XI. CONCLUSION

Based upon the results of animal, biomechanical and clinical testing the ISKD System has the mechanical properties to perform its intended use of limb lengthening of the tibia and femur and is considered to be substantially equivalent to the predicate devices 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 - 2 2001

Mr. Carl Knobloch
Vice President and General Manager
Orthodyne Inc.
1118 South Orange Avenue, Suite 204
Orlando, Florida 32806

Re: K010322
Trade Name: ISKD Intramedullary Skeletal Kinetic Distractor
Regulation Number: 888.3020
Regulatory Class: II
Product Code: HSB
Dated: January 22, 2001
Received: February 2, 2000

Dear Mr. Knobloch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

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): K010322

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: Yes

(Per 21 CFR 801.109)

Or

Over-The-Counter No

(Optional Format 1-2-96)

Miriam C. Provost

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

510(k) Number K010322