510K SUMMARY

K080542

Submitter of 510k: Emily B. Rossiter on behalf of John W. King, DDS

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DEC 15 2008

Date of Summary: August 20, 2008

Trade Name: Distrax™

Classification Name: External Mandibular Fixator and/or Distractor

Device Product Code: MQN

Predicate Device: Modus Modular Distraction Osteogenesis System (K051946)

Intended Use: The Distrax is intended for mandibular symphyseal widening and mandibular lengthening by distraction osteogenesis. Following the distraction osteogenesis, the Distrax may also be used for temporary stabilization during the consolidation phase. The Distrax is intended for single patient use only.

Device Description:
Distrax™ is a preassembled distraction system consisting of the following major components: Distraction Screw, Distractor Arms, Fixed Screw, Threaded Tube, Locknut (optional). Titanium Bone Screws (K063298) and brackets (surgical stainless steel, 24 gauge) are required for use and should be obtained by the surgeon and orthodontist, respectively. An Activation Key is also supplied to turn the Distraction Screw. The patient contact materials of the Distrax are made of austenitic stainless steel type 304 (chromium-nickel stainless class) and type 316 (chromium-nickel class containing 2-3% molybdenum). These materials are specified in ISO standards 5832-1 and 5832-9 for medical implant applications. The device must be cleaned and sterilized before use.

Comparison with Predicate Device:
The Distrax Intraoral Distractor is substantially equivalent to the Modus Modular Distraction Osteogenesis System (K051946). Equivalence is based on similarities in intended use, materials of construction, design, and operating principles, as summarized in the following table. The major differences between the Distrax and the Modus are that the Distrax is intended for mandibular symphyseal widening and mandibular lengthening by distraction osteogenesis and is pre-assembled and customized to fit each patient. The

Modus is modular, requiring assembly and intraoperative fitting to the patient's bone structure; the Modus is intended for use in both mandibular and maxillary osteogenesis procedures, and fractures.

Feature	Distrax	Modus Modular Distraction Osteogenesis System - K051946
Intended Use	The Distrax is intended for mandibular symphyseal widening and mandibular lengthening by distraction osteogenesis. Following the distraction osteogenesis, the Distrax may also be used for temporary stabilization during the consolidation phase.	Subcutaneous distractor system intended for use in fractures, osteotomies, and arthrodeses; for use in the mandible and maxilla. The Modus Modular Distractor is intended for mandibular symphyseal widening by distraction osteogenesis.
Material	Stainless steel	Implant steel and titanium
Design	Preassembled and customized distractor with four arms, fixed and distraction screws, threaded tube, locknut (optional) and activation key to turn the distraction screw.	Plates, distraction cylinders, flexible extensions offered in a variety of sizes; allow adjustment of the vector by intra-operative bending if necessary.
Operational Principles	The Distrax is a customized, preassembled, combination tooth and bone-borne appliance which is pre-fit to each patient, based upon mandibular impression and x-rays provided with the prescription. The Distrax is attached to the mandibular symphysis by titanium bone screws and to the mandibular teeth with circumferential stainless steel wires. A hexagonal distraction screw connects the fixed screw on one side of the appliance to the threaded tube on the other side. The activation wrench is utilized, making turns on the hexagonal distraction screw until the desired bone lengthening is achieved. The Distrax is then secured with the locking screw and left in place for stabilization and adequate bone healing.	The Modus is used for various applications of the maxillofacial bone structures. The cylinders, which are available in uni-directional or bi-directional design, with multiple distraction lengths, are used with the Modus plates and screws for gradual bone distraction osteogenesis and for corrective osteotomies of the mandible and maxilla.
Supplied Sterile?	No; instructions for sterilization provided	No
Single Use?	Yes	Not known

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2008

John W. King
C/o Dr. Emily B. Rossiter
President
Regulatory Resources, Incorporated
800 East Leigh Street, Suite 206-5
Richmond, Virginia 23219

Re: K080542
Trade/Device Name: Distrax ™
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: December 11, 2008
Received: December 12, 2008

Dear Dr. King:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K080542

Device Name: Distrax™

Indications for Use:

The Distrax is intended for mandibular symphyseal widening and mandibular lengthening by distraction osteogenesis. Following the distraction osteogenesis, the Distrax may also be used for temporary stabilization during the consolidation phase. The Distrax is intended for single patient use only.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R Petz DDS for Dr. Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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