K993869

JAN 19 2000

TAB 5

510(k) SUMMARY

Inter-Os Technologies, L.L.C.
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Aurora, CO 80016-2126

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Contact:
Randolph C. Robinson, M.D.,D.D.S.
303-699-7970
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Summary Prepared Nov 6, 1999

Device Identification:

Trade Name-	Inter-Os Bone Generator™
Common Name-	Internal Bone Distractor
Classification Name-	Single/Multiple component metallic bone fixation Appliance and accessories, 21 CFR 888.3030

The Inter-Os Bone Generator™ is compared to the Howmedica Leibinger MID System, the Synthes Mandibular Distractor, the KLS Martin Mandibular Distractor, and the Howmedica Mandibular Distractor. We believe the Inter-Os device to be substantially equivalent based on the descriptive characteristics, same intended use, and same principle of operation of distraction osteogenesis, as described in the 510(k) comparative matrix included in this section.

The Inter-Os Bone Generator™ is an implantable device used to treat conditions where bone growth is deficient. It is used for the distraction osteogenesis techniques in the facial bones and implanted by a plastic surgeon. The device is to be removed after distraction is complete. It features two telescoping components that are distracted apart by a threaded drive shaft. Activation of the drive shaft is by means of a transcutaneous pin which may be removed once the distraction phase is complete. The activation pin and drive shaft are articulated using an internal gear.

All of the components of the Inter-Os Bone Generator™ are fabricated from stainless steel.

The Inter-Os Bone Generator™ is intended to be sold non-sterile. Sterilization instructions are included in the labeling. It is a single-use device.

Performance has been substantiated by mechanical tests, animal studies, and In vivo patient trials which are included in the submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2000

Randolph C. Robinson, M.D., D.D.S.
Manager
Inter-Os Technologies, L.L.C.
7144 South Chapparal Circle East
Aurora, Colorado 80016-2126

Re: K993869
Trade Name: Inter-Os Bone Generator™
Regulatory Class: II
Product Code: MQN
Dated: November 6, 1999
Received: November 15, 1999

Dear Dr. Robinson:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: pending

Device Name: Inter-Os Bone Generator™

Indications for Use:

The Inter-Os Bone Generator™ is an implantable device for distraction osteogenesis techniques in the facial bones implanted by a surgeon. Distraction osteogenesis involves making an osteotomy through the bone and then slowly moving the bone ends apart. The result is a stretching of the bone callus so that new bone is generated in the gap. This technique is well-established and follows the principles of Illizarov. (See Addendum A Osteogenesis Research Bibliography)

The Inter-Os Bone Generator™ is used to treat conditions where bone growth is deficient. The types of deformities that fall into this category are:

various forms of otomandibular syndrome, hemifacial microsomia, Treacher-Collins syndrome, condylar agenesis, craniosynostosis, Apert's syndrome, Crouzon's syndrome, Pfeiffer's syndrome, etc.

The application of the device is done in place of bone grafting to augment deficient areas of bone growth. The advantages of distraction bone generation are that the patient is spared the morbidity of additional surgical sites and native autogenous bone is formed. The device can also be used in post-traumatic deformities, such as condylar fractures in children.

The Bone Generator™, therefore, is intended to be used in the various bones of the craniofacial region, such as the mandible, zygoma, maxilla, frontal bone, parietal bone, and the temporal bone. It is not the current intended use to apply the Bone Generator™ to the long bones of the limbs or in the spine, but only to the bones of the craniofacial region.

The Bone Generator™ is intended for single use and is not meant for repeat sterilization and implantation. The device is to be removed after distraction stabilization is complete. It is to be used with other commercially-available accessory devices, such as bone screws for fixation to the bone surface. The device is not meant to be fixated to the bone with bone cement, however, it is possible that commercially-available bone cement may be used on the undersurface of the device to level or stabilize it on a curved surface.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) X OR Over-The-Counter Use_____

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K99 3869