Section 1.3

Summary of Safety and Effectiveness

REGULATORY AUTHORITY

Safe Medical Devices Act of 1990, 21 CFR 807.92

COMPANY NAME/CONTACT

Terry Knapp, MD
OrthoNetx, Inc.
1000 S. McCaslin Blvd,
Suite 300
Superior, CO 80027
Voice: 303.494.1681 x 301
FAX: 303.494.1714

NAME OF DEVICE

Trade Name: *GenerOs*™ SB Small Bone Distraction Implant
Common Name: Internal Bone Plate Distractor

Common Description: Single/Multiple component metallic bone fixation appliance and accessories

Classification Names:

Regulation Number	Product Code	Classification Name	Device Class
21 CFR 888.3030	KTT	Appliance, fixation, nail/blade/plate combination, multiple component	II
21 CFR 888.3030	HRS	Plate, Fixation, Bone	II

DEVICE DESCRIPTION

GenerOs SB is an implantable device made of surgical grade stainless steel for deficiencies of small bones of the extremities. It features two telescoping component bone plates that are distracted apart by a threaded drive shaft. The activation pin and the drive shaft are articulated using an internal gear. The device has a fixation plates on the activation and sliding block, and if not used for fixation of the device, may be easily removed. Activation of the drive shaft occurs through a transcutaneous pin, which is removed once the distraction phase is complete. The *GenerOs SB* implant is removed after distraction and consolidation are complete. The *GenerOs SB* includes reusable instruments such as activation, insertion / removal tools and other surgical instruments.

GenerOs SB is a single-use device, sold non-sterile, and requires sterilization prior to use. It is. Sterilization instructions are included in the labeling.

INDICATION FOR USE STATEMENT

The *GenerOs SB* is an implantable device for distraction osteogenesis techniques in the small bone of the extremities. *GenerOs SB* is used to treat conditions where small bones of the extremities are deficient. The types of deformities that fall into this category include, but are not limited to:

- Congenital deficiencies of the bones of the forearms, wrists, ankles, hands and feet;
- Post-traumatic deficiencies of the bones of the forearms, wrists, ankles, hands and feet;
- Deficiencies of the bones of the forearms, wrists, ankles, hands and feet due to tumor resection.

Each *GenerOs SB* is intended for single use only. The device is to be removed after distraction and bone stabilization are 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 intended to be fixed 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.

PREDICATE DEVICES

- *GenerOs* Bone Generator; OrthoNetx, Inc. (formerly Inter-Os Technologies) (#K993869)
- Limb Lengthener; OrthoNetx, Inc, (#K031875)
- Arthrex Small Fragment Plates and Screws; Arthrex, Inc., (#K040907)
- Lorenz Small Fragment System (#K992961); Walter Lorenz Surgical, Inc.
- LCP Modular Foot Plates; Synthes (USA), (#K050110)

SUBSTANTIAL EQUIVALENCE COMPARISON

The *GenerOs* SB is identical in features and technology to the GenerOs CF Craniofacial Bone Generator (#K993869); the only difference is the indication for use.

The features and indications for use are compared to OrthoNetx' Limb Lengthener (#K031875).

Indications for use are compared to Arthrex Small Fragment Plates and Screws by Arthrex, Inc., (#K040907); Lorenz Small Fragment System (#K992961) by Walter Lorenz Surgical, Inc. and LCP Modular Foot Plates by Synthes (USA), (#K050110).

The *GenerOs* SB is substantially equivalent to predicate devices based on the descriptive characteristics, similar intended use, and same principle operation of distraction osteogenesis.

PERFORMANCE

Performance of the *GenerOs SB* has been substantiated by biocompatibility, sterilization, packaging validation, and mechanical tests in conformance to standard testing guidelines for bone plate implant devices.

CONCLUSION

Based on the design, materials, function, intended use, the *GenerOs SB* is substantially equivalent to the devices currently cleared under the Federal Food, Drug and Cosmetic Act. The *GenerOs SB* Distraction Implant raises no new safety or effectiveness issues. Therefore, safety and effectiveness are reasonably assured, justifying 510(k) clearance for the *GenerOs SB* Distraction Implant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2005

Terry Knapp, M.D.
CEO
OrthoNetX, Inc.
1000 S. McCaslin Blvd.
Suite 300
Superior, Colorado 80027

Re: K051162
Trade/Device Name: GenerOs™ SB Small Bone Distraction Implant
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT, HRS
Dated: May 4, 2005
Received: May 5, 2005

Dear Dr. Knapp:

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.

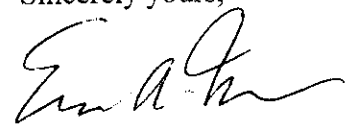
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 1.2

Indications for Use Statement

510(k) Number: _____

Device Name: *GenerOs*™ SB Small Bone Distraction Implant

Indications for Use:

The *GenerOs* SB is an implantable device for distraction osteogenesis techniques in the small bone of the extremities. *GenerOs SB* is used to treat conditions where small bones of the extremities are deficient. The types of deformities that fall into this category include, but are not limited to:

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Prescription Use___XX___ **or** **Over-The-Counter Use**_____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)