

SANATMETAL



Manufacturer of Orthopaedic and Traumatologic Products
 H-3301, Eger Faiskola út 5. Phone: +(36)36-512-900 Fax: +(36)36-
 512-932 www.sanatmetal.hu e-mail: metal@sanatmetal.hu

510(k) Statement of Summary

- A 510(k) Owner Sanatmetal Manufacturer of Orthopaedic And Traumatologic Products
 3300 Eger
 Faiskola u. 5
 Hungary
- Contact Donald W. Guthner
 Orgenix, LLC
 111 Hill Road
 Douglassville, PA 19518
 (888) ORGENIX (674-3649)
 (484) 363-5879 (FAX)
dg@orgenix.com
- Preparation Date December 23, 2007
- B Trade Name Intramedullary Nails and Pins
- Common Name Intramedullary Nails, Nails
- Classification Intramedullary Fixation Rod
 21 CFR 888.3020
 Product Code: HSB
- C Predicate Device(s) Substantial equivalence for *SanatMetal Intramedullary Nails and Pins* is based on its similarities in indications for use, design features, operational principles and material composition when compared to the predicate devices cleared under the following submissions:
- K051557, TriGen® Retrograde Femoral, Supracondylar and Tibial Nails;
 - K032722, TriGen® Straight Humeral Nail System;
 - K040212, TriGen® InterTAN;
 - K023115, Ace® VersaNail; and
 - K983942, Intramedullary Nail System

FEB - 7 2008

- D Device Description

The device is a stainless steel or titanium alloy nail for orthopaedic implantation.
Depending on the model selected, the device may have none, any or all of the following features: cannulation, endcaps, slots, holes, anodized finish (titanium models only), locking screws.

- E Intended Use

Indications for the *Sanatmetal Intramedullary Nails and Pins* include traumatologic implants for the intramedullary fixation of fractures of tubular bones (femur, tibia, humerus), nonunions and malunions, i.e. diaphysis fractures, sub-trochanter fractures and femoral sub-trochanter fractures combined with diaphysis fractures, extra- and intraarticular fractures.

Sanatmetal Intramedullary Nails and Pins are single use devices.

- F Technological Characteristics

As was established in this submission, the subject device is substantially equivalent to other devices cleared by the agency for commercial distribution in the United States.

Engineering drawings, labeling, and mechanical testing have demonstrated that the subject device is substantially equivalent, if not identical, to its predicate devices in terms of design, materials of composition, indications for use, and such other characteristics as may be associated with the manufacture of any medical device.

- G Non-Clinical Testing

FDA Recognized Performance Standards

 - ◆ ASTM F1264-03

- H Clinical Testing

Not applicable to this device

- I Conclusions

Based on the 510(k) Summary and the information provided herein, we conclude that the *Sanatmetal Intramedullary Nails and Pins* are substantially equivalent to the existing legally marketed devices under the Federal Food, Drug and Cosmetic Act.

- J Additional Information

NA



FEB - 7 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Orgenix, LLC
% Mr. Donald Guthner
111 Hill Road
Douglassville, PA 19518

Re: K070761
Trade/Device Name: Sanatmetal Intramedullary Nails and Pins
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: February 4, 2008
Received: February 5, 2008

Dear Mr. Guthner:

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.

Page 2 - Mr. Donald Guthner

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) 276-0120. 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,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070761

Device Name: Sanatmetal Intramedullary Nails and Pins

Indications for Use:

Indications for the *Sanatmetal Intramedullary Nails and Pins* include traumatologic implants for the intramedullary fixation of fractures of tubular bones (femur, tibia, humerus), nonunions and malunions, i.e. diaphysis fractures, sub-trochanter fractures and femoral sub-trochanter fractures combined with diaphysis fractures, extra- and intraarticular fractures.

Sanatmetal Nails and Pins are single use devices.

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)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K070761