5. 510(k) Summary

Company:

NovaLign™ Orthopaedics, Inc.
5885 Ridgeway Center Parkway - Suite 210
Memphis, TN 38120
Phone: (901) 213-5151
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FEB - 9 2009

Contact:

Jeffrey G. Roberts
President & CEO

Prepared By:

Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street, NW, 12th Floor
Washington, DC 20005
Phone: (202) 552-5800
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Device Name: Intramedullary Fixation System

Classification: 21 CFR 888. 3020, Intramedullary fixation rod, Class II

Product Code: HSB

Device Description: The NovaLign™ Intramedullary Fixation System is a segmented, intramedullary nail intended for long bone fracture fixation. The device is intended to function as a flexible intramedullary nail during device placement, but will be made rigid at the completion of the surgical implantation procedure.

Intended Use: The NovaLign™ Intramedullary Fixation System is intended for use in the fixation of long bone fractures, including fractures in the humerus, femur and the tibia.

Materials: The implants are made from titanium alloy (ASTM F136) and Nitinol (ASTM F2063)

Substantial Equivalence: Comparative information presented in the 510(k) supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 2009

NovaLign Orthopaedics, Inc.
% Mr. Jeffrey G. Roberts
President & CEO
5885 Ridgeway Center Parkway – Suite 210
Memphis, Tennessee 38120

Re: K083458
Trade/Device Name: Intramedullary Fixation System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulation Class: Class II
Product Code: HSB
Dated: January 16, 2009
Received: January 16, 2009

Dear Mr. Roberts:

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) 276-0120. 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

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

Enclosure

4. Indications for Use

510(k) Number (if known): K083458

Device Name: **NovaLign™ Intramedullary Fixation System**

The NovaLign™ Intramedullary Fixation System is intended for use in the fixation of long bone fractures, including fractures in the humerus, femur and the tibia.

Prescription Use √ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K083458