MAY - 9 2003

K031156

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
Navitrack™ System – FluoroSpine

Applicant: ORTHOsoft Inc.
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Montreal, Quebec
Canada, H3C 2N6
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Contact Person: Christopher McLean

Date Summary Prepared: April 9, 2003

Device Trade Name: Navitrack™ System – FluoroSpine

Device Classification Name: Stereotaxic Instrument (84 HAW); 21 CFR § 882.4560

Predicate Device:
Navitrack System™ – Optical Option, from Orthosoft Inc, 510(k) # K002053

Device Description:
The Navitrack™ System – FluoroSpine device consists of a software-driven workstation, an optical tracking system, surgical instruments, and tracking accessories. It is designed to assist the surgeon in the placement of spine reconstruction components relative to the vertebrae. Tracking devices are incorporated with given surgical instruments, as well as on to bases that attach to the vertebrae, such to allow the ability to track and display to the user their respective positions intra-operatively. The vertebrae are displayed to the user as based on a fluoroscopic image obtained at the beginning of the procedure. Given instrument and implant components that need to be positioned are schematically represented superimposed on the vertebrae image to depict their relative locations.

Indications for Use / Intended Use:
The Navitrack™ System - FluoroSpine is a stereotaxic instrument indicated for use in precisely positioning instruments or implants during orthopaedic surgery, such as operations performed within spinal structures.
The Navitrack™ System enables the surgeon to review radiology images from different modalities in 2D and 3D display. This system also enables the surgeon to virtually manipulate bone structures as reconstructed from these modalities in order to perform preoperative planning.

This is identical to the Navitrack System™ – Optical Option predicate.

Technological Comparisons to the Predicates:
The comparisons showed that the proposed device is substantially equivalent to the Navitrack System – Optical Option. It is a modification to the predicate. The fundamental scientific technology of the Navitrack predicate is unchanged. It utilizes the same workstation, tracking technology, and instruments. The modification consists in using images obtained from a fluoroscope to depict the tracked vertebrae, as compared to using model depictions reconstructed from CT-scans as in the Navitrack. This involved changes to the software and the inclusion of accessories. The new accessories involve a device to calibrate and correct the distortion of the source x-ray image and correct the image projection plane during navigation, and an x-ray detector device to trigger the system to record the image when the user activates the fluoroscope. In addition, changes to the ergonomics of the software user interface were incorporated to improve user-friendliness.

Performance Data:
Non-clinical tests were performed to assess that no new safety and efficacy issues were raised in the device. They consisted in verifying that the accuracy and performance of the system was adequate as compared to the predicate.

Conclusion:
The information and data provided in this 510(k) Premarket Notification established that the proposed Navitrack™ System – FluoroSpine device is substantially equivalent to the Navitrack System™ – Optical Option predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Christopher McLean, Eng.
Regulatory Affairs and
Quality Assurance Manager
ORTHOsoft, Inc.
75, Queen Street, Suite 3300
Montréal, Quebec
Canada H3C2N6

Re: K031156
Trade/Device Name: Navitrak™ System-FluoroSpine
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: April 10, 2003
Received: April 14, 2003

Dear Mr. McLean:

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 (301) 594-4659. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K031156

Device Name: Navitrack™ System – FluoroSpine

Indications for Use:
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use_____
(per 21CFR 801.109)

Miriam C. Provost

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

510(k) Number K031156