JAN 1 4 2005

K043536

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Navitrack® System – S&N Image Free Knee

Applicant: ORTHOsoft Inc.
75 Queen Street, suite 3300
Montreal, Quebec
Canada, H3C 2N6
Tel.: 514 861 4074
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Contact Person: Christopher McLean

Date Summary Prepared: December 21, 2004

Device Trade Name: Navitrack® System – S&N Image Free Knee

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

Predicate Device:
Navitrack® System – Optical TKR CT-Less; from Orthosoft Inc; 510(k) # K021760.

Device Description:
Identically as in the predicate, the Navitrack® System – S&N Image Free Knee device consists of a software-driven workstation, an optical tracking system, surgical instruments, and tracking accessories, designed to assist the surgeon in the placement of Total Knee Replacement (TKR) components. Tracking devices are incorporated with given surgical instruments, as well as on to fixation bases that attach to each of the femur and tibia, such to allow the ability to track and display to the user their respective positions intra-operatively. The femur and tibia are displayed to the user in the form of their main alignment axes. The alignment axes are determined and recorded intra-operatively by identifying the key anatomical references that are used clinically to align and position the TKR components. The instruments are schematically represented.
The main modifications to the predicate are to incorporate a new set of instruments to be tracked corresponding to assisting the placement of two new TKR implant lines.

Indications for Use / Intended Use:
The Navitrack® System – S&N Image Free Knee is indicated for use as a stereotaxic instrument to assist in the positioning of Total Knee Replacement components intra-operatively.
It is a computer controlled image-guidance system equipped with a three-dimensional tracking sub-system. It is intended to assist the surgeon in determining reference alignment axes in relation to anatomical landmarks, and in precisely positioning the alignment instruments relative to these axes by displaying their locations.

This is identical to the predicate.

Technological Comparisons to the Predicate:
The fundamental scientific technology of the predicate is unchanged. The intended use, the indications, along with the main operating principle and control mechanism, are maintained in the proposed device to perform the same surgery to provide the same image guidance assistance in the placement of TKR orthopedic implants. The main changes to the predicate generally included secondary engineering and software modifications in relation to navigating two new implant lines. In addition, the software was modified to increase the joint laxity information provided for ligament balance assistance, and the calibration/registration method for one of the instruments was modified.

Performance Data:
Non-clinical tests were performed to assess that no new safety and efficacy issues were raised in the device. These included tests and analyses to verify that the accuracy and performance of the system was adequate for its intended use and not reduced in comparison to the predicate.

Conclusion:
The information and data provided in this 510(k) Premarket Notification established that the Navitrack® System – S&N Image Free Knee device is substantially equivalent to the Navitrack® System – Optical TKR CT-Less predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2005

Mr. Christopher McLean, Eng.
Regulatory Affairs and
Quality Assurance Director
ORTHOsoft, Inc.
75, Queen Street, Suite 3300
Montréal, Quebec
Canada H3C 2N6

Re: K043536
Trade/Device Name: Navitrack® System - S&N Image Free Knee
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: December 21, 2004
Received: December 22, 2004

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 (240) 276-0115. 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

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: K043536

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Prescription Use ✓ OR Over-the-Counter Use _____
(per 21CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043536