K071714

JUL 20 2007

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Navitrack® System – OS Unicondylar Knee Universal

Applicant: ORTHOsoft Inc.
75 Queen Street, suite 3300
Montreal, Quebec
Canada, H3C 2N6
Tel.: 514 861 4074
Fax: 514 866 2197

Contact Person: Christopher McLean

Date Summary Prepared: June 21, 2007

Device Trade Name: Navitrack® System – OS Unicondylar Knee Universal

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

Predicate Devices:
1) Navitrack® System – OS Knee Universal; from Orthosoft Inc; 510(k) # K060336
2) Uni Knee Surgetics Navigation System; from Praxim; 510(k) # K062146

Device Description:
The Navitrack® System – OS Unicondylar Knee Universal device consists of software, a computer workstation, an optical tracking system, surgical instruments, and tracking accessories, designed to assist the surgeon in the placement of unicondylar knee replacement 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 components.

Indications for Use / Intended Use:
The Navitrack® System – OS Unicondylar Knee Universal is indicated for use as a stereotaxic instrument to assist in the positioning of unicondylar 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.

Technological Comparisons to the Predicate:
The fundamental scientific technology of the predicates is unchanged. The main operating principle and control mechanism are maintained in the proposed device to similarly provide image guidance assistance in the placement of knee orthopedic implants.
While maintaining the same main software features and many of the same instrument components, the OS Knee Universal predicate was modified with secondary instrumentation and software changes to accommodate more specifically the requirements of unicondylar knee replacement techniques as compared to those of bicondylar (total) knee components in the OS Knee Universal predicate.
The main changes to the OS Knee Universal are as follows.

- A new function was added to provide an estimate from the navigation data for the hip-knee-ankle alignment simultaneously while aligning the saw guides.
- Alternate alignment axes were included to help to axially orient and position the posterior femoral cut in comparison to the axial rotation,
- Minor changes and improvement were incorporated in the instrument used to navigate the saw guides from the implant systems, and the instrument used to digitize the cut surfaces was reduced to cover a single condyle instead of the predicate two-condyle design.

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 OS Knee Universal predicate.

Conclusion:
The information and data provided in this 510(k) Premarket Notification established that the Navitrack® System – OS Unicondylar Knee Universal Knee device is substantially equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 2007

ORTHOsoft, Inc.
% Mr. Christopher McLean
RA/QM Director
75 Queen Street, Suite 3300
Montréal, Quebec
Canada H3C 2N6

Re: K071714
Trade/Device Name: Navitrack® System – OS Unicondylar Knee Universal
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: June 21, 2007
Received: June 22, 2007

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 (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

510(k) Number: K071714

Device Name: Navitrack® System - OS Unicondylar Knee Universal

Indications for Use:

The Navitrack® System – OS Unicondylar Knee Universal is indicated for use as a stereotaxic instrument to assist in the positioning of unicondylar 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K071714