K030827

MAY 2 3 2003

SECTION 2: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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: March 12, 2002

Device Trade Name: Navitrack™ System – Total Hip Replacement CT-Free Cup

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

Predicate Devices: Navitrack System™ – Total Hip Replacement; from Orthosoft Inc; 510(k) #K022364

Device Description:
The Navitrack™ System – Total Hip Replacement CT-Free Cup 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 Total Hip Replacement (THR) components. Tracking devices are incorporated with given surgical instruments, as well as on to fixation bases that attach to the pelvis, such to allow the ability to track and display to the user their respective positions intra-operatively. The pelvis is displayed to the user in the form of its 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 THR components. The instruments are schematically represented.

Indications for Use / Intended Use:
The Navitrack™ System – Total Hip Replacement CT-Free Cup is indicated for use as a stereotaxic instrument to assist in the positioning of hip replacement components.
It is a computer controlled image-guidance system equipped with a three-dimensional tracking sub-system. It is intended to assist in precisely positioning hip replacement components intra-operatively by displaying their positions relative to the joint's alignment axes as based on user-identified anatomical landmarks.

Technological Comparisons to the Predicate:
The comparisons showed that the proposed device is substantially equivalent to the Navitrack System – Total Hip Replacement predicate. It is a modification to the predicate. The fundamental scientific technology of the predicate is unchanged. It utilizes the same workstation and tracking technology. The main difference is in the technique with corresponding changes in the software. Instead of determining the alignment axes from 3-D model representations of the bones of interest that were created from CT-Scan images pre-operatively, in the proposed device the alignment axes are determined by digitizing key anatomical landmarks directly on the bone of interest intra-operatively. The instruments are equivalent incorporating minor modifications in relation to the new proposed technique.

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 Navitrack™ System – Total Hip Replacement CT-Free Cup device is substantially equivalent to the Navitrack System™ – Total Hip Replacement predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2003

Mr. Christopher McLean, Eng.
Regulatory Affairs &
Quality Assurance Manager
Orthosoft, Inc.
75, Queen Street, Suite 3300
Montréal, Quebec
Canada H3C 2N6

Re: K030827
Trade/Device Name: Navitrack™ System-Total Hip Replacement CT-Free Cup
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: March 12, 2003
Received: March 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,

for Miriam C. Provost

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:

Device Name: Navitrack™ System – Total Hip Replacement CT-Free Cup

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ 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 K030827