K021760 AUG 27 2002

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
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Contact Person: Christopher McLean

Date Summary Prepared: May 27, 2002

Device Trade Name: Navitrack™ System – Optical TKR CT-Less

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

Reason for 510(k) Notification: Modifications of indications and technology to a currently cleared device from Orthosoft Inc.

Susbtantial Equivalence Claimed To:
The Navitrack System™ – Optical Option, from Orthosoft Inc. (K002053)
The Orthopilot®, from Kinamed Inc. (K003347)

Device Description:
The Navitrack™ System – Optical TKR CT-Less device consists of a computer workstation, an optical tracking system, surgical instruments, and tracking devices. It is designed to assist the surgeon in the placement of Total Knee Replacement (TKR) components. Intra-operatively, the tracking devices are attached to the femur and the tibia, and to the alignment and pointing instruments, in order to track and display their relative locations in real-time. The pointing instruments are used to digitize the relative locations of anatomical landmarks that are commonly used clinically for TKR alignment. In the case of the femoral head landmark, it is computed by the system as based on a motion analysis of the femur. From the landmarks the system then computes and displays the alignment axes. The alignment instrument is then navigated and positioned relative to these axes on each bone which in turn sets the placement of the cutting guides.

Indications for Use / Intended Use:
The Navitrack™ System – Optical TKR CT-Less 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.

Technological Comparisons to Substantial Equivalent Devices:
The comparisons showed that the proposed product is equivalent to both the Navitrack and the Orthopilot predicates in terms of the workstation and the tracking technology. The main departures of the proposed product relative to the Navitrack predicate related to its intended use in TKR procedures, and to the technology change of navigating relative to knee alignment axes instead of 3D bone models reconstructed pre-operatively. These new elements were however found to be equivalent to the Orthopilot predicate.

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 to perform as intended.

Conclusion:
The information and data provided in this 510(k) Premarket Notification established that the Navitrack™ System – Optical TKR CT-Less device is substantially equivalent to the legally marketed predicates: the Navitrack System™ – Optical Option, and the Orthopilot®.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2002

ORTHOsoft Inc.
Christopher McLean
Regulatory Affairs & Quality Assurance Manager
75, Queen Street, suite 3300
Montreal, Quebec
Canada H3C 2N6

Re: K021760
Trade/Device Name: Navitrack™ System Optical TKR CT-Less
Regulation Number: 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: HAW
Dated: May 27, 2002
Received: May 29, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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" (21 CFR Part 807.97). 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

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: K021760

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

510(k) Number K021760