FEB 0 4 2003

K022364

# 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**: July 19, 2002

**Device Trade Name**: Navitrack™ System – Total Hip Replacement

**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 VectorVision® Hip, from BrainLAB AG (K010602)

**Device Description**:
The Navitrack™ System – Total Hip Replacement 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 onto 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 bones of interest are displayed to the user as three-dimensional (3D) surface models, while the instruments are schematically represented. Models of the implant are also represented in order to visualize their placement using the instruments. The 3D models of the pelvis are reconstructed pre-operatively from given CT-images using image processing tools provided with the software. The software also provides planning features by allowing the user to determine pre-operatively an ideal location for the implants as based on the models.

**Indications for Use / Intended Use**:
The Navitrack™ System – Total Hip Replacement 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 that integrates a three-dimensional tracking sub-system and image-processing software. It is intended to assist in precisely

positioning hip replacement components intra-operatively by displaying their positions relative to the bone structures of interest that are modeled pre-operatively from radiology images.

**Technological Comparisons to Substantial Equivalent Devices**:
The comparisons showed that the proposed product is equivalent to both the Navitrack and the VectorVision Hip predicates in terms of the workstation and the tracking technology. The only significant departures of the proposed product relative to the predicates consisted in the intended use of the proposed device in THR procedures unlike in the Navitrack predicate. However, the VectorVision Hip predicate includes this intended use as well as also being otherwise equivalent.

**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 – Total Hip Replacement device is substantially equivalent to the legally marketed predicates: the Navitrack System™ – Optical Option, and the VectorVision® Hip.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 4 2003

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

Re: K022364
Trade/Device Name: Navitrack System Total Hip Replacement, Model 900.200
Regulation Number: 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: November 5, 2002
Received: November 6, 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Mark N Melkerson

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

**Indications for Use:**
The Navitrack™ System – Total Hip Replacement 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 that integrates a three-dimensional tracking sub-system and image-processing software. It is intended to assist in precisely positioning hip replacement components intra-operatively by displaying their positions relative to the bone structures of interest that are modeled pre-operatively from radiology images.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

for Mark N Milhous

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

510(k) Number K022364