

ORIGINAL 510K SUBMISSION  
NAVITRACK™ COMPUTER-ASSISTED SURGERY SYSTEM

**SECTION 2 : 510(K) SUMMARY**

K981315

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and CFR § 807.92.

**A. SUBMITTER INFORMATION**

1. Company Name : ORTHOsoft Inc.
2. Company Address : 40, Bates Road, suite 240  
Outremont, Quebec  
Canada, H2V 1A8
3. Company Phone : (514)-276-4074
4. Contact Person : Nicole Landreville, Eng.I.T.  
Quality Manager  
ORTHOsoft Inc.
5. Date Summary Prepared : April 8<sup>th</sup>, 1998

**B. DEVICE IDENTIFICATION**

1. Proprietary Name : Navitrack™ System
2. Classification Name : Stereotaxic Instrument (84 HAW) ;  
21 CFR § 882.4560

**C. IDENTIFICATION OF PREDICATE DEVICES**

The Navitrack™ System is substantially equivalent to the following legally marketed devices :

- The Regulus™ Navigator from COMPASS International Inc. (K964229), determined to be substantially equivalent to a legally marketed device on August 19, 1997.
- The Surgical Microscope Navigator System from Zeiss (K965139), determined to be substantially equivalent to a legally marketed device on April 23, 1997.

## **D. DEVICE DESCRIPTION**

The main components of the Navitrack™ system are:

### **D.1. Computer Workstation and device display**

All the software implemented by ORTHOsoft and part of the Navitrack™ system resides and runs on a computer workstation. The computer is installed inside the device chassis and is linked to position sensors fixed on the surgical tools via cable, in order to follow surgeon movements.

### **D.2. Localization System**

The localization system is made of a **Position Sensor Unit** (Magnetic Field Digitizer) and the **Navitrack™ Software**. Since the positioning sensors have the ability to measure six degrees of freedom, only one of these sensors will be required to monitor the 3 dimensional position and the attitude of each tool.

The electromagnetic transmitter and receivers are connected to electronic units, which perform position computations and relay information to the workstation.

### **D.3. Tools and instruments**

The computer software is adapted to the surgical equipment. Electromagnetic receivers are fixed to the surgical tools. In order to follow the bone structure movements, a positioning sensor mounted onto a reference clamp is attached to the bone to be instrumented.

## **E. INTENDED USE**

The Navitrack™ System is a stereotaxic instrument indicated for use in precisely positioning instruments or implants during orthopedic surgery, such as operation performed within spinal structures.

The Navitrack™ System enables the surgeon to review radiology images from different modalities in two-dimensional and three-dimensional display. This system also enables the surgeon to virtually manipulate bone structures as reconstructed from these modalities in order to perform pre-operative planning.

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## F. COMPARISON WITH SUBSTANTIALLY EQUIVALENT DEVICES

The Navitrack™ is substantially equivalent to the following legally marketed predicate devices :

- The Navitrack™ System is substantially equivalent to the **Zeiss Surgical Microscope Navigator (SMN) System** with regard to its intended use which is navigational support during surgery. Both systems are indicated for use in orthopedic surgery.
- The Navitrack™ System is substantially equivalent to the **Compass Regulus™ Navigator** with regard to its basic functions as a computer-assisted surgery system that incorporates a reconstruction software module intended to visualize the structure orientation within the anatomy of the human body

The Navitrack™ System, the **Zeiss Surgical Microscope Navigator System** and the **Regulus™ Navigator** are stereotaxic instruments intended to provide the surgeon with navigational support during surgery. Basically, these systems assist surgery by virtually displaying simultaneously the surgical tools and the structure of interest.

*Differences that exist between these systems and Navitrack™ relate to physical appearance and materials, options and accessories, and control systems. They do not affect the relative safety or effectiveness of the Navitrack™ System.*

## G. TECHNOLOGICAL CHARACTERISTICS

The fundamental technical characteristics of the Navitrack™ are similar or identical to those of the predicate devices and are listed on the comparison table provided in this submission. Technical differences that exist between these systems do not affect the relative safety or effectiveness of the Navitrack device.

## H. PERFORMANCE DATA

Performance tests were done on the Navitrack™ System.

These tests along with clinical studies demonstrate that the Navitrack™ System is safe and accurate in performing the stated intended use.

The results of those tests and studies are attached to this submission.

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## **I. PREMARKET NOTIFICATION 510(k) CHECKLIST**

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided at the beginning of this submission.

## **J. CONCLUSION**

The information and data provided in this 510(k) Notification establish that the Navitrack™ System is substantially equivalent to the legally marketed predicate devices.



JUL 9 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Nicole Landreville, Eng.I.T.  
•Quality Manager  
Orthosoft, Inc.  
40 Bates Road, Suite 240  
Outremont, Quebec  
Canada, H2V 1A8

Re: K981315  
Trade Name: Navitrack  
Regulatory Class: II  
Product Code: HAW  
Dated: April 8, 1998  
Received: April 10, 1998

Dear Ms. Landreville:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

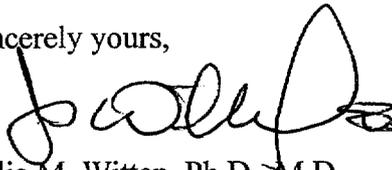
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

  
h Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

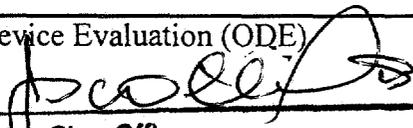
April 8<sup>th</sup>, 1998

510(k) Number :

Device Name : Navitrack™ System

Indications for Use : The Navitrack™ System is a stereotaxic instrument indicated for use in precisely positioning instruments or implants during orthopedic surgery, such as operation perform within spinal structures.

(Concurrence of CDRH, Office of Device Evaluation (ODE))

  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K981315

Prescription Use    
(Per 21 CFR 801.109)

OR

Over-the-Counter Use