5. 510(K) SUMMARY

K103829

APR - 4 2011

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92(c).

APPLICANT	OrthAlign, Inc. 120 Columbia Suite 500 Aliso Viejo, CA 92656 Tel: (949) 715-2424 Fax: (949) 831-9500
OFFICIAL CORRESPONDENT	Amy Walters AWE, Inc. 338 Vista Madera Newport Beach, CA 92660 amy@orthalign.com Tel: (949) 923-9400 Fax: (949) 831-9500
TRADE NAME	KneeAlign® 2 System
COMMON NAME	Stereotaxic Instrument
DEVICE CLASSIFICATION	Class II, 21 CFR §882.4560
PRODUCT CODES	OLO: Orthopedic Stereotaxic Instrument
PREDICATE DEVICES	KneeAlign System with Reference Sensor (K093998) Navitrack System- S&N Image Free Knee (K043536)

SUBSTANTIALLY EQUIVALENT TO:

The KneeAlign® 2 System is substantially equivalent to the previously cleared KneeAlign System with Reference Sensor (K093998) and Navitrack System- S&N Image Free Knee (K043536).

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The KneeAlign® 2 System is an innovative non-invasive computer assisted surgical navigation system for use in knee arthroplasty procedures. The KneeAlign® System is configured to detect, measure, and display angular measurement changes in a triaxial format.

The current standard of care for knee arthroplasty procedures has the physician estimating these changes either by visual observation and tactile feedback or with

assistance of computer assisted surgery devices. The KneeAlign® 2 System utilizes a palm-sized computer module and reference sensor to generate positional information in orthopedic procedures providing a sequence of steps for registration of anatomical landmarks, calculation of mechanical axes, and positioning of instruments relative to the mechanical axes. In knee arthroplasty procedures, the device assists the surgeon in:

- Establishing the mechanical axis of the femur, determining the varus/valgus angle and the flexion/extension angle of the cutting block relative to femur.
- Establishing the mechanical axis of the tibia, determining the varus/valgus angle and the posterior slope angle of the cutting block relative to tibia.

The KneeAlign® 2 System comprises a single use computer module and reusable instrumentation.

INDICATIONS FOR USE:

The KneeAlign®2 System has the same indications for use as the previously cleared KneeAlign™ System with Reference Sensor (K093998). Additional functionality has been added to the predicate device to enable femoral navigation. Also, Indications for Use are common to the Navitrack System- S&N Image Free Knee (K043536). Thus, the Indications for Use are as follows:

The KneeAlign® 2 System is a computer-controlled system intended to assist the surgeon in determining reference alignment axes in relation to anatomical structures during stereotactic orthopedic surgical procedures. The KneeAlign® 2 System facilitates the accurate positioning of implants and instrumentation, relative to these alignment axes. Example orthopedic surgical procedures include but are not limited to:

- Total Knee Arthroplasty

TECHNICAL CHARACTERISTICS:

The KneeAlign® 2 System comprises a single use computer module, a reusable reference sensor, a reusable femoral jig and a reusable tibial jig. The device utilizes algorithms to convert sensor outputs into spatial coordinates, providing graphical representation of instruments and anatomy on the user display screen.

PERFORMANCE DATA:

Device performance testing confirms that the KneeAlign® 2 System can be used according to its intended use. The KneeAlign® 2 System has been verified and validated according to OrthAlign's procedures for product design and development. Performance testing included:

- Software verification and validation
- System hardware verification/validation testing

- Electrical safety and electromagnetic compatibility testing
- System accuracy testing
- Simulated use testing

This testing regime demonstrates that the subject device is substantially equivalent to the legally marketed predicate devices, for its intended use in facilitating the accurate positioning of implants and instrumentation, relative to reference alignment axes.

The information provided by OrthAlign in this 510(k) application was found to be substantially equivalent to predicate devices such as the KneeAlign® System with Reference Sensor (K093998), and Navitrack System- S&N Image Free Knee (K043536).

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

A technological comparison and bench, and cadaver testing demonstrate the substantial equivalence of the KneeAlign® 2 System to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OrthAlign, Inc.
% AWE, Inc.
Ms. Amy Walters
338 Vista Madera
Newport Beach, California 92660

APR - 4 2011

Re: K103829
Trade/Device Name: KneeAlign® 2 System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 23, 2011
Received: March 24, 2011

Dear Ms. Walters:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K103829

Device Name: KneeAlign® 2 System

Indications for Use:

The KneeAlign® 2 System is a computer controlled system intended to assist the surgeon in determining reference alignment axes in relation to anatomical structures during stereotactic orthopedic surgical procedures. The KneeAlign® 2 System facilitates the accurate positioning of implants and instrumentation, relative to these alignment axes. Example orthopedic surgical procedures include but are not limited to:

- Total Knee Arthroplasty

Prescription Use __x____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for ma

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103829