1DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 2, 2017

OrthAlign, Inc.
% David Vancelette
Director QA/RA
Orthalign, Inc.
120 Columbia, Suite 500
Aliso Viejo, California 92656

Re: K163379
Trade/Device Name: KneeAlign 2 System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 30, 2016
Received: December 1, 2016

Dear David Vancelette:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163379

Device Name
KneeAlign 2 System

Indications for Use *(Describe)*

The KneeAlign® 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 system facilitates the accurate positioning of implants and instrumentation, relative to these alignment axes.

Orthopedic surgical procedures include but are not limited to:
- Total Knee Arthroplasty
- Unicompartmental Knee Arthroplasty – Tibial Transverse Resection

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. 510(K) SUMMARY

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

DATE	November 30, 2016
APPLICANT	OrthAlign, Inc. 120 Columbia Suite 500 Aliso Viejo, CA 92656 Tel: (949) 715-2424 Fax: (949) 831-9500
OFFICIAL CORRESPONDENT	David Vancelette OrthAlign, Inc. 120 Columbia, Suite 500 Aliso Viejo, CA 92656 dvancelette@orthalign.com Tel: (949) 525-9034 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	OrthAlign Plus® System (K153237) KneeAlign® 2 System (K103829)
SUBMISSION TYPE	Traditional 510(k). The subject device is a modification to the previously cleared KneeAlign® 2 System (K103829).

SUBSTANTIALLY EQUIVALENT TO:

The KneeAlign® 2 System is substantially equivalent to the previously cleared KneeAlign® 2 System (K103829) and OrthAlign Plus® System (K153237).

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

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

format.

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

In unicompartmental knee arthroplasty procedures, the device assists the surgeon in:

- Establishing the mechanical axis of the tibia, determining the varus/valgus angle and the posterior slope angle of the cutting block relative to the tibia, for the transverse resection.

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® 2 System (K103829). Additional functionality has been added to the predicate device to enable the navigation of tibial transverse resections in unicompartmental knee arthroplasty. Also, Indications for Use are common to the OrthAlign Plus® System (K153237). Thus, the Indications for Use are as follows:

KneeAlign® 2 System:

The KneeAlign® 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 system facilitates the accurate positioning of implants and instrumentation, relative to these alignment axes.

Orthopedic surgical procedures include but are not limited to:

- Total Knee Arthroplasty
- Unicompartmental Knee Arthroplasty – Tibial Transverse Resection

TECHNICAL CHARACTERISTICS (COMPARED TO PREDICATE):

The KneeAlign® 2 System was cleared under K103829. 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 and numerical representation of instruments and

anatomy on the user display screen. The KneeAlign® 2 System is being updated to include navigation functionality for unicompartmental knee arthroplasty, as in the predicate device OrthAlign Plus® System (K153237). All other features and principles of operation remain unchanged.

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 addressed only the added Unicompartmental instruments and surgical procedure steps. Performance testing included:

- System hardware verification/validation testing to ensure the instruments meet their mechanical requirements.
- Instrumentation cleaning, sterilization and shipping validations for the specified processes.
- Navigation device sterilization, packaging, shelf life, environmental conditions and shipping validations for the specified ranges of conditions involved in each process. (Summary data for the identical predicate device is referenced.)
- System components biocompatibility assessment per ISO 10993-1 (2009).
- Customer requirements / usability validation in cadaver with an advising surgeon to validate the system meets design input requirements for its functions in a simulated use environment.
- System accuracy testing: bench testing with mechanical fixtures and foam models to verify navigated resection plane angular and depth accuracy.

For simulated use testing, a prospective cadaver validation was done in a simulated operating room environment with a surgeon conducting the procedures.

This testing regime demonstrates that the subject device is as safe and effective as the predicate devices. This testing regime demonstrates that the subject device is substantially equivalent to the legally marketed predicate devices, for its intended use in the accurate navigation of tibial resection planes in unicompartmental knee arthroplasty.

The information provided by OrthAlign in this 510(k) application confirms that the KneeAlign® 2 System is substantially equivalent to predicate devices such as the KneeAlign® 2 System (K103829) and OrthAlign Plus® System (K153237).

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

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

SECTION 5. 510(K) SUMMARY

The subject device is identical to the predicate KneeAlign® 2 System (K103829), with the following exceptions:

- The subject device allows for the navigation of the tibial transverse resection plane in unicompartmental knee arthroplasty.

The subject device is substantially equivalent in terms of unicompartmental knee arthroplasty function to the predicate device OrthAlign Plus® System (K153237).

The table below summarizes the features of the subject device as compared to the predicate devices.

SECTION 5. 510(K) SUMMARY

Table 1. KneeAlign® 2 System Comparison to Predicates

Property	KNEEALIGN® 2 SYSTEM	KNEEALIGN® 2 SYSTEM (K103829) PREDICATE 1	ORTHALIGN PLUS® SYSTEM (K153237) PREDICATE 2
Indications for Use	Total Knee Arthroplasty / Unicompartmental Knee Arthroplasty: The KneeAlign® 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 system facilitates the accurate positioning of implants and instrumentation, relative to these alignment axes. Orthopedic surgical procedures include but are not limited to: • Total Knee Arthroplasty • Unicompartmental Knee Arthroplasty – Tibial Transverse Resection	Total Knee Arthroplasty The KneeAlign® 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 system facilitates the accurate positioning of implants and instrumentation, relative to these alignment axes. Orthopedic surgical procedures include but are not limited to: • Total Knee Arthroplasty ➢ *Unicompartmental Knee Arthroplasty function is being added.*	Total Knee Arthroplasty / Total Hip Arthroplasty / Unicompartmental Knee Arthroplasty: The OrthAlign Plus® System is a computer-controlled system intended to assist the surgeon in determining reference alignment axes in relation to anatomical and instrumentation structures during stereotactic orthopedic surgical procedures. The OrthAlign Plus® System facilitates the accurate positioning of implants, relative to these alignment axes. The system aids the surgeon in controlling leg length and offset discrepancies in Total Hip Arthroplasty. Example orthopedic surgical procedures include but are not limited to: • Total Knee Arthroplasty • Total Hip Arthroplasty: Anterior/Posterior • Unicompartmental Knee Arthroplasty: Tibial transverse resection ➢ *Same Indications for Use.*

SECTION 5. 510(K) SUMMARY

Property	KNEEALIGN® 2 SYSTEM	KNEEALIGN® 2 SYSTEM (K103829) PREDICATE 1	ORTHALIGN PLUS® SYSTEM (K153237) PREDICATE 2
Technological Principles			
Computer generation of positional information	Uses inertial sensors, microcontroller and digital signal processor to generate positional information.	Identical	Identical
Registration of anatomy	Lateral and medial malleoli and the center of the tibial plateau are registered to establish a tibial reference frame.	Identical	Identical
Navigation of tibial transverse resection plane	Posterior slope is in the sagittal plan of the tibia. Varus/Valgus is in the coronal plane of the tibia.	Identical	Identical
Controls resection depth	Via mechanical instruments	Identical	Identical
Surgical work flow	• Patient preparation • Instrument setup • Instrument attachment to patient • Anatomic registrations • Cutting block navigation • Resection	Identical	Identical
Design Elements			
Main System Components	• Single-use computer unit • Navigation software • Reusable instrument set • Registration instruments • Cutting blocks	Identical	Identical
User Interface	Integrated graphical user interface, on single-use unit that attached to instrumentation.	Identical	Identical
Tibial Cutting Blocks	Mechanical instrument that interfaces with tibial jig for variable positioning	Identical	Identical