November 22, 2017

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

Re: K172462
Trade/Device Name: OrthAlign Plus® System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 11, 2017
Received: August 14, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172462

Device Name

OrthAlign Plus® System

Indications for Use *(Describe)*

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. Ligament balancing is provided by the OrthAlign Plus® System in primary or revision Total Knee 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
- Ligament Balancing

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5. K172462 510(K) SUMMARY

1. 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	October 21, 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: (858) 692-0335 Fax: (949) 831-9500
TRADE NAME	OrthAlign Plus® System
COMMON NAME	Stereotaxic Instrument
DEVICE CLASSIFICATION	Class II, 21 CFR §882.4560
PRODUCT CODES	OLO: Orthopedic Stereotaxic Instrument
PREDICATE DEVICES	OrthAlign Plus® System (K171780) Brainlab DASH Knee (K102251) OrthoSensor VERASENSE Knee System (K150372)
SUBMISSION TYPE	Traditional 510(k). The subject device is a modification to the previously cleared OrthAlign Plus® System (K171780).

SUBSTANTIALLY EQUIVALENT TO:

The OrthAlign Plus® System is substantially equivalent to the previously cleared OrthAlign Plus® System (K171780), Brainlab DASH Knee (K102251) and OrthoSensor VERASENSE Knee System (K150372).

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

SECTION 5. 510(K) SUMMARY

The OrthAlign Plus® System is a non-invasive computer assisted surgical navigation system for use in knee and hip arthroplasty procedures. The OrthAlign Plus® System is configured to detect, measure, and display angular and positional measurement changes in a triaxial format. The OrthAlign Plus® 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 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.
- Measuring the angles and gap distances between the femur and proximal tibia, for use in ligament balancing and establishing a reference line to assist in setting the rotation of the femoral implant, in primary or revision procedures.

In hip arthroplasty procedures, the device assists the surgeon in:

- Establishing the orientation of the anterior pelvic plane and determining the inclination angle and the anteversion angle of the shell impactor relative to the anterior pelvic plane, or to the anterior pelvic plane adjusted for pelvic tilt.
- Measuring the intraoperative change in leg length and offset.

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 OrthAlign Plus® System comprises a single use computer module and reusable instrumentation.

INDICATIONS FOR USE:

The OrthAlign Plus® System has the same indications for use as the previously cleared OrthAlign Plus® System (K171780). Additional functionality has been added to the predicate device to provide ligament balancing and measurements of bone alignment in total knee arthroplasty. Also, Indications for Use are common to the Brainlab DASH Knee (K102251) and OrthoSensor VERASENSE Knee System (K150372). Thus, the Indications for Use are as follows:

OrthAlign Plus® System:

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. Ligament balancing is provided by the OrthAlign Plus® System in primary or revision Total Knee 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
- Ligament Balancing

TECHNICAL CHARACTERISTICS (COMPARED TO PREDICATE):

The OrthAlign Plus® System was cleared under K171780. The OrthAlign Plus® System comprises a single use computer module, a reusable reference sensor, a reusable laser module, a reusable femoral jig, a reusable tibial jig, a reusable posterior hip jig and a reusable anterior hip 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 OrthAlign Plus® System is being updated for total knee arthroplasty approach to include measurement of bone alignment and ligament balancing, as in the predicate device Brainlab DASH Knee (K102251), and for the application of measurement of bone alignment and ligament balancing in primary or total knee arthroplasty, as in the predicate OrthoSensor VERASENSE Knee System (K150372). All other features and principles of operation remain unchanged.

PERFORMANCE DATA:

Device performance testing confirms that the OrthAlign Plus® System can be used according to its intended use. The OrthAlign Plus® System has been verified and validated according to OrthAlign's procedures for product design and development. Performance testing addressed the new functionality and surgical procedure steps. Performance testing included:

- Software verification and validation to ensure the integrity of the code and functionality and reliability of the software in various use sequences.
- System hardware verification/validation testing to ensure the instruments meet their mechanical requirements.
- Instrumentation cleaning, sterilization and shipping validations or adoptions for the specified processes.
- System components biocompatibility assessment per ISO 10993-1 (2009).
- System accuracy testing: bench testing with mechanical fixtures to verify gap distance and angle measurement accuracy.
- Simulated use testing in cadaver with an advising surgeon to validate the system meets requirements for user needs and usability in a simulated use environment.

This testing regime demonstrates that the subject device is as safe, as effective, and performs as well as the predicate devices. This testing regime demonstrates that the subject device is

SECTION 5. 510(K) SUMMARY

substantially equivalent to the legally marketed predicate devices, for its intended use in the measurement of bone alignment and ligament balancing in TKA.

The information provided by OrthAlign in this 510(k) application confirms that the OrthAlign Plus® System is substantially equivalent to predicate devices such as the OrthAlign Plus® System (K171780) and Brainlab DASH Knee (K102251) and OrthoSensor VERASENSE Knee System (K150372).

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

A technological comparison and bench and cadaver testing demonstrate the substantial equivalence of the OrthAlign Plus® System to the predicate devices.

The subject device is identical to the predicate OrthAlign Plus® System (K171780), with the following exception: the subject device allows for the measurement of bone alignment and ligament balancing in TKA.

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

SECTION 5. 510(K) SUMMARY

Table 1. OrthAlign Plus® System Comparison to Predicates

Feature or Principle	Subject Device: OrthAlign Plus System	Predicate OrthAlign Plus System (K171780)	Predicate Brainlab DASH Knee (K102251)	Predicate OrthoSensor VERASENSE Knee System (K150372)
Materials	• Stainless Steel grades common to orthopedic surgical instruments • Polymer grades common to orthopedic surgical instruments • Internal electronics	Identical	Identical	Similar: • Polymer grades common to orthopedic surgical instruments • Internal electronics
Control Mechanism	Computer generation of positional information, using inertial sensors, microcontroller, digital signal processor and physical positions of registration instruments.	Identical	Similar. Uses stereoscopic camera, reflective trackers and computer to generate positional information, based on physical positions of registration instruments.	Similar: Computer generation of positional information using pressure sensors and physical position of registration instrument.
Operating Principles Registration of anatomy	Electronics attached to movable instruments, placed in specified procedural positions, on or in contact with bony anatomy, for recording sensor data.	Identical	Similar. Optical registration of identical indicated anatomic points and instrument orientations.	Similar: Electronics attached to movable instruments, placed in specified procedural positions, in contact with trials or implants, for recording sensor data.
Measurement of change in distance	• Computer displayed values. • Optical camera reading of instrument position (for distance). • Accelerometer measurement of	Identical	Similar. Uses stereoscopic camera, reflective trackers and computer to generate positional information, based on physical	N/A

Feature or Principle	Subject Device: OrthAlign Plus System	Predicate OrthAlign Plus System (K171780)	Predicate Brainlab DASH Knee (K102251)	Predicate OrthoSensor VERASENSE Knee System (K150372)
	angular change in instrument positions.		positions of registration instruments.	
Measurement of change in angular orientations	• Computer displayed values based on internal calculations. • Accelerometer measurement of angular change in instrument positions.	Identical	Similar, with: • Computer displayed values based on internal calculations. • Stereoscopic camera identification of reflective tracker positions on registration instruments.	Similar, with: • Computer displayed values based on internal calculations. • Load sensor determination of contact points.
Main System Components	• Single-use computer unit • Navigation and measurement software • Reusable instrument sets	Identical	Similar: reusable computer console instead of single-use unit. Other elements identical.	Similar: • Single-use electronic unit • Measurement software • Reusable computer console
User Interface	Integrated graphical user interface, on an electronic unit that attaches to instrumentation.	Identical	Similar, with the addition of a separate computer console with a graphical user interface	Similar, with the addition of a separate computer console with a graphical user interface
Energy Type	• Navigation unit, reference sensor and laser module: DC battery power. • Instruments: manual	Identical	Similar, with: • Electronic user interface (in the surgical field):	Identical for: • Single-use electronic module: DC battery power.

SECTION 5. 510(K) SUMMARY

Feature or Principle	Subject Device: OrthAlign Plus System	Predicate OrthAlign Plus System (K171780)	Predicate Brainlab DASH Knee (K102251)	Predicate OrthoSensor VERASENSE Knee System (K150372)
	positioning and manipulation.		Identical. • Instruments: Identical • Computer console: AC power.	
Sterilization	• Navigation unit: EO sterilization. • Instruments: autoclave sterilization	Identical	Similar, with: • Electronic user interface (in the surgical field): sterile draping. • Instruments: Identical	Identical for: • Single-use electronic module: EO sterilization.
Biocompatibility	Per ISO 10993-1, External Communicating Device, Tissue/Bone/Dentin Communicating, with subsystems that have direct and potential indirect contact for a limited contact duration (< 24 hours)	Identical	Identical	Identical
Patient interface	Instrument fixation to bone with pins or screws. Instrument indications and engagement of bony anatomy via physical surface contact.	Identical	Identical	Similar: Instrument insertion in the joint, with physical contact to trials or implants
Environmental specifications	Specified storage and operating environments for typical transport and surgical environments.	Identical	Identical	Identical