DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 11, 2017

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

Re: K171780
Trade/Device Name: OrthAlign Plus System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 14, 2017
Received: June 15, 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.

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,

Vincent J. Devlin -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171780

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.

Example orthopedic surgical procedures include but are not limited to:
- Total Knee Arthroplasty
- Total Hip Arthroplasty: Anterior/Posterior
- 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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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	June 14, 2017
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 DEVICE	OrthAlign Plus® System (K162962)
SUBMISSION TYPE	Special 510(k): Device Modification. The subject device is a modification to the previously cleared OrthAlign Plus® System (K162962).

SUBSTANTIALLY EQUIVALENT TO:

The OrthAlign Plus® System is substantially equivalent to the previously cleared OrthAlign Plus® System (K162962).

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

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.

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 (K162962).

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.

Example orthopedic surgical procedures include but are not limited to:

- Total Knee Arthroplasty
- Total Hip Arthroplasty: Anterior/Posterior
- Unicompartmental Knee Arthroplasty: Tibial transverse resection

TECHNICAL CHARACTERISTICS (COMPARED TO PREDICATE):

The OrthAlign Plus® System was cleared under K162962. 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 the total hip arthroplasty: posterior approach to include navigation of the shell impactor to the table (or coronal) reference plane, and to enable the measurement of intraoperative change in leg length and offset using a laser to guide repositioning of the leg as in the previously cleared predicate device OrthAlign Plus® System (K162962) when used for total hip arthroplasty: anterior approach. 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.
- Customer requirements validation 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 leg length and offset and updated scale reader measurement accuracy.

This testing regime demonstrates that the subject device is as safe, as effective, and performs as well as the predicate device. This testing regime demonstrates that the subject device is substantially equivalent to the legally marketed predicate device, for its intended use in facilitating the accurate measurement of intraoperative change in leg length and offset and navigation of the acetabular shell impactor relative to the anterior pelvic plane established by the table reference frame, in THA, posterior approach.

The information provided by OrthAlign in this 510(k) application confirms that the modified OrthAlign Plus® System is substantially equivalent to predicate device, the OrthAlign Plus® System (K162962).

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

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

The subject device is identical to the predicate OrthAlign Plus® System (K162962), with the following exceptions:

- The subject device allows for the navigation of the acetabular shell impactor relative to the anterior pelvic plane established by the table reference frame, in THA, posterior approach.
- The subject device uses a laser to facilitate repositioning of the leg and single point femur registration for the measurement of intraoperative changes in leg length and joint offset in THA, posterior approach.

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

Table 1. OrthAlign Plus® System Comparison to Predicate

Feature or Principle	Modified Device	Predicate OrthAlign Plus System (K162962)
Materials	Identical	• 17-4 PH Stainless Steel H900 • 316L Stainless Steel • 455 Stainless Steel • 455 Stainless Steel • 300 Series Stainless Steels • Nitronic 60 • Solvay Radel R-5000 • Solvay Radel R-5100 • Solvay Radel R-5500 • POM C Acetal Copolymer • Polyester, Autoflex-EBA • Lexan HP1-7H8D330 • Internal electronics
Control Mechanism - shell impactor navigation	Identical Identical	• Computer measurement of the shell impactor's orientation during acetabular shell implantation. • Computer displayed anteversion and abduction angles for the shell impactor.
Control Mechanism - leg length & offset change measurements	Identical Identical	• Computer displayed length (superior-inferior) and offset (medial-lateral) changes. • Computer calculation of the intraoperative change in position of the femur.
Operating Principles Computer generation of positional information	Identical	Uses inertial sensors, microcontroller and digital signal processor to generate positional information, based on physical positions of registration instruments.

Feature or Principle	Modified Device	Predicate OrthAlign Plus System (K162962)
Registration of anatomy	Identical	Electronics attached to movable instruments, placed in specified procedural positions for recording sensor data.
Femur registration	Identical to the predicate's anterior approach	• Physically registers a fiduciary plate: instrument temporarily attaches to the femur. • Anterior approach: physically registers a fiduciary point: instrument attached to the femur.
Leg positioning	Identical to the predicate's anterior approach	• Posterior approach: visual positioning and registration of a reference plane used to locate leg. • Anterior approach: Laser crosshair pattern used to locate leg.
Main System Components	Identical Identical Identical Identical Identical	• Single-use computer unit • Navigation software • Reusable instrument set • Registration instruments • Acetabular Shell Impactor
User Interface	Identical	Integrated graphical user interface, on single-use unit that attaches to instrumentation.
Energy Type	Identical	• Navigation unit, reference sensor and laser module: DC battery power. • Instruments: manual positioning and manipulation.
Sterilization	Identical	Navigation unit: EO sterilization. Instruments: autoclave sterilization
Biocompatibility	Identical	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)
Patient interface	Identical	Instrument fixation to bone with pins or screws. Probe indications of acetabular anatomy.
Environmental specifications	Identical	Specified storage and operating environments for typical transport and surgical environments.