DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 23, 2017

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

Re: K162962
Trade/Device Name: Orthalign Plus System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 21, 2016
Received: October 24, 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)*

K162962

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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K162962

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	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 (K153237) Stryker Navigation System – CT Based Hip Module (K050615)
SUBMISSION TYPE	Traditional 510(k). The subject device is a modification to the previously cleared OrthAlign Plus® System (K153237).

SUBSTANTIALLY EQUIVALENT TO:

The OrthAlign Plus® System is substantially equivalent to the previously cleared OrthAlign Plus® System (K153237) and Stryker Navigation System – CT Based Hip Module (K050615).

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 (K153237). Additional functionality has been added to the predicate device to enable the measurement of intraoperative change in leg length and offset and navigation of the shell impactor to an alternate reference plane in total hip arthroplasty: anterior approach. Also, Indications for Use are common to the Stryker Navigation System – CT Based Hip Module (K050615). 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.

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 K153237. The OrthAlign Plus® System comprises a single use computer module, a reusable reference sensor, 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 hip arthroplasty: anterior approach to include navigation of the shell impactor to an alternate reference plane, as in the predicate device Stryker Navigation System – CT Based Hip Module (K050615), and enable the measurement of intraoperative change in leg length and offset using a laser to guide repositioning of the leg, 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 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 electronics hardware meets its mechanical requirements.
- Electrical safety testing to IEC 60601-1:2005 + Corr. 1 (2006) + Corr. 2 (2007) + AM1 (2012) or IEC 60601-1:2012.
- Electromagnetic compatibility testing to IEC 60601-1-2: 2015.
- Laser product safety verification to IEC 60825-1:2014.
- 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 for some validations.)
- System components biocompatibility assessment per ISO 10993-1 (2009).
- 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.

- Simulated use testing in cadaver to validate system accuracy vs. the gold standard of radiographic measurement in a simulated use environment (see discussion below).

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

Measurement of the intraoperative change in leg length and offset was validated for the anterior approach with 40 data points (on 5 hips), using radiographic evaluation of the leg length and offset changes.

Navigation of the acetabular shell insertion relative to the anterior pelvic plane adjusted for pelvic tilt was validated for the anterior approach with 38 data points (on 5 hips), using radiographic evaluation of the cup placement angles.

This testing regime demonstrates that the subject device is as safe, as effective, and performs as well as or better than 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 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 adjusted for pelvic tilt, in THA, anterior approach.

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 (K153237) and Stryker Navigation System – CT Based Hip Module (K050615).

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 (K153237), with the following exceptions:

- The subject device allows for the measurement of intraoperative changes in leg length and joint offset in THA, anterior approach.
- The subject device uses a laser to facilitate repositioning of the leg for the measurement of intraoperative changes in leg length and joint offset in THA, anterior approach.
- The subject device allows for the navigation of the acetabular shell impactor relative to the anterior pelvic plane adjusted for pelvic tilt, in THA, anterior approach.

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 Components, Classes & Clearances – Summary

Property	SUBJECT DEVICE ORTHALIGN PLUS® SYSTEM	PREDICATE 1 ORTHALIGN PLUS® SYSTEM (K153237)	PREDICATE 2 Stryker Navigation System – CT Based Hip Module (K050615)
Indications for Use	Total Knee Arthroplasty / Total Hip 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	Total Knee Arthroplasty /Total Hip 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: Posterior. Example orthopedic surgical procedures include but are not limited to: • Total Knee Arthroplasty • Total Hip Arthroplasty: Anterior/Posterior • Unicompartmental Knee Arthroplasty: Tibial transverse resection	Total Hip Arthroplasty: The Navitrack Stryker Navigation System – CT Based Hip Module is intended as a planning and intraoperative guidance system to enable open or percutaneous computer assisted surgery. The system is indicated for any medical condition in which the use of computer assisted surgery may be appropriate, and where a reference to a rigid anatomical structure such as but not limited to the pelvis, or femur, can be identified. The system shall be operated only by trained personnel such as orthopedic surgeons and clinical staff. The Stryker Navigation System – Hip Module supports, but is not limited to the following surgical procedures • Any form of Total Hip Arthroplasty (THA), e.g. open or minimally invasive • Precisely position instruments, implants and bony tissue during orthopedic surgery, such as operations performed with Hip and bones in the upper extremities • Revisions

SECTION 5. 510(K) SUMMARY

Property	SUBJECT DEVICE ORTHALIGN PLUS® SYSTEM	PREDICATE 1 ORTHALIGN PLUS® SYSTEM (K153237)	PREDICATE 2 Stryker Navigation System – CT Based Hip Module (K050615)
Technological Principles			
Computer generation of positional information	Uses inertial sensors, microcontroller and digital signal processor to generate positional information, based on 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.
Registration of anatomy	Ipsilateral ASIS, contralateral ASIS and pubic symphysis are registered to establish a pelvic reference frame, which can be rotated normal to the gravity vector, to adjust for pelvic tilt.	Similar. Identical registrations and anterior pelvic reference frame.	Similar. Optical registration of identical indicated anatomic points. Computer generation of identical anterior pelvic reference frame. Similar adjustment for pelvic tilt.
Navigation of acetabular shell impactor	With anteversion and abduction angles	Identical	Identical
Measurement of intraoperative changes in leg length and offset	For total hip arthroplasty: posterior and anterior approaches	Similar: for total hip arthroplasty: posterior approach	Identical
Surgical work flow	• Patient preparation • Instrument setup • Instrument attachment to patient • Anatomic registrations • Joint preparation • Implant navigation • Measurement of changes in leg position	Identical	Identical
Design Elements			

SECTION 5. 510(K) SUMMARY

Property	SUBJECT DEVICE ORTHALIGN PLUS® SYSTEM	PREDICATE 1 ORTHALIGN PLUS® SYSTEM (K153237)	PREDICATE 2 Stryker Navigation System – CT Based Hip Module (K050615)
Main System Components	• Single-use computer unit • Navigation software • Reusable instrument set • Registration instruments • Acetabular Shell Impactor	Identical	Similar: reusable computer console instead of single-use unit. Other elements identical.
ser Interface	Integrated graphical user interface, on single-use unit that attached to instrumentation.	Identical.	Similar: graphical user interface on reusable console screen outside the sterile field.
Femur registration	Physically registers a fiduciary point: instrument attaches to the femur.	Similar: physically registers a fiduciary plate: instrument temporarily attaches to the femur.	Similar: optically registers a fiduciary element: instrument attaches to the femur.
Leg positioning	Laser crosshair pattern used to locate leg.	Similar: visual positioning and registration of a reference plane used to locate leg.	Similar: visual positioning and registration of a reference plane used to locate leg.