April 10, 2020

OrthAlign, Inc.
Karyl Haskell
Vice President Regulatory Affairs and Quality Assurance
120 Columbia, Suite 500
Aliso Viejo, California 92656

Re: K200642
Trade/Device Name: OrthAlign Plus System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 9, 2020
Received: March 11, 2020

Dear Karyl Haskell:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*

K200642

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 discrepancy 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.

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

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OrthAlign, Inc
Special 510(k) Premarket Notification
OrthAlign HipAlign® Sterile Pin Pack

510(k) Summary

Applicant	OrthAlign, Inc 120 Columbia, Suite 500 Aliso Viejo CA 92656
Official Correspondent:	Karyl Haskell Vice President, Regulatory Affairs/Quality Assurance
Phone:	949.715.2424
Email:	khaskell@orthalign.com
Address:	120 Columbia, Suite 500 Aliso Viejo CA 92656
Date	9 March 2020
TRADE NAME	OrthAlign® HipAlign® Sterile Pin Pack
COMMON NAME	Stereotaxic Instrument
DEVICE CLASSIFICATION	Class II, 21 CFR §882.4560
PRODUCT CODES	OLO: Orthopedic Stereotaxic Instrument
PRIMARY PREDICATE DEVICE Reference Device(s)	OrthAlign Plus® System (K171780) K163627 Shotel Ankle Arthrodesis Nail System K162674 Biopro Food Plating Systems K132510 Biopro Infinity plate anchor system
SUBMISSION TYPE	Special 510(k) Device Modification. The subject device is a modification to the previously cleared OrthAlign Plus® System (K171780).

SUBSTANTIALLY EQUIPVALENT TO:

The OrthAlign Plus® System is substantially equivalent to the previously cleared OrthAlign Plus® System (K171780).

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.

The OrthAlign HipAlign® Sterile Pin Pack is a set of sterile, single use pins used in conjunction with the OrthAlign Plus® system of instruments and electronics. The OrthAlign® HipAlign® Pin Pack includes:

- Pelvic Fixation pins: 4.0mm in diameter and 90mm to 140mm in length
- Pelvic Fixation pins: 5mm in diameter and 170mm in length
- Femoral registration markers: 4.0mm to 4.5mm in diameter and 16mm to 25mm in length

INDICATIONS FOR USE

The OrthAlign HipAlign® Sterile Pin Pack is indicated for use with the 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 discrepancy 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

Intended Use: The OrthAlign® HipAlign® Sterile Pin Pack is intended to be used with the OrthAlign Plus® system specific to Total Hip Arthroplasty.

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, and reusable instruments.

The OrthAlign Plus® System is being updated to provide sterile, single use fixation pins and femoral registration markers for use in total hip arthroplasty. All other features and principals of operation remain the same.

PERFORMANCE DATA:

Performance testing of the packaging materials confirm that the OrthAlign® HipAlign® Sterile Pin Packs can be used according to its intended use. The packaging has been verified and validated according to OrthAlign's procedures for product design and development. The sterilization of the product has been validated. Performance testing included:

- Environmental conditioning and distribution simulation

- Package integrity testing (visual, dye penetration test, and peel strength testing)

This testing demonstrates that the pins and markers are as safe and effective as the predicate device. This testing regime demonstrates that the modified device is substantially equivalent to the legally marketed predicate device, for its intended use in detecting, measuring, and displaying angular and positional measurement changes in a triaxial format. The information provided by OrthAlign in this 510(k) notification confirms that the modified OrthAlign Plus® instruments are substantially equivalent to the predicate device, the OrthAlign Plus® System (K171780).

BASIS FOR DETERMINATION OF SUBSTANIAL EQUIVALENCE

A technological comparison and performance testing demonstrate the substantial equivalence of the OrthAlign® HipAlign® Sterile Pin packs to the instruments in the predicate device.

The subject devices are identical to the predicate OrthAlign Plus® System (K171780), with the following exceptions:

- The subject devices are provided as sterile, single-use devices whereas the predicate devices are provided as non-sterile, reusable devices.

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

Table 1HipAlign Sterile Pin Pack Comparison to Predicate

Feature or Principal	Predicate OrthAlign Plus® System K171780	Modified Device
Materials	Stainless steel • 17-4PH H900 per ASTM A564, passivated per ASTM A967 • 316 Stainless Steel, passivated per ASTM A976	Identical
Operating Principals	• Markers – assist in obtaining leg length/offset measurements • Pins – secure instruments to bones Markers and Pins are removed at the conclusion of the procedure	Identical
Sterilization	Non-sterile reusable	EtO sterilized, single use
Packaging	Surgical Instrument Tray	HDPE Packaging Card Tyvek Pouch (inner and outer)
Shelf life	Not applicable	7-year shelf life