June 18, 2020

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

Re: K200892
Trade/Device Name: Harvey(R) Surgical Assistant
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 22, 2020
Received: May 22, 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, M.P.H.
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)*
K200892

Device Name
Harvey(R) Surgical Assistant System

Indications for Use *(Describe)*
The HSA 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 HSA system facilitates the accurate positioning of implants, relative to these alignment axes.

Example 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.

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."

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

DATE: 21 May 2020

APPLICANT

OrthAlign, Inc.
120 Columbia, Suite 500
Aliso Viejo CA 92656
Tel:
Fax: 949.831.9500

OFFICIAL CORRESONDENT

Karyl Haskell
Vice President of Regulatory Affairs and Quality Assurance
120 Columbia Suite 500
Aliso Viejo CA 92646
Tel: (949) 715-2424
Fax: (949) 831-9500

DEVICE CLASSIFICATION	Class II, 21 CFR 882.4560
PRODUCT CODES	OLO: Orthopedic Stereotaxic Instrument
COMMON NAME	Orthopedic Stereotaxic Instrument
TRADE NAME	OrthAlign Harvey® Surgical Assistant (HAS) System
PRIMARY PREDICATE DEVICE	OrthAlign Plus System (K162962)
Reference Device	OrthAlign Plus System (K130387)

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 Harvey® Surgical Assistant System is substantially equivalent to the previously cleared OrthAlign Plus® System (K162962).

DEVICE DESCRIPTION

The OrthAlign Harvey® Surgical Assistant System is a non-invasive computer assisted surgical navigation system for use in total knee and Unicompartmental knee arthroplasty procedures. The Harvey® Surgical Assistant System is configured to detect, measure, and display angular and positional measurement changes in a triaxial format. The Harvey® Surgical Assistant 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 arthropolasty 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 Harvey® Surgical Assistant System comprises a single use computer module and reusable instrumentation.

INDICATIONS FOR USE

The Harvey Surgical Assistant has the same indications for total knee and unicompartmental knee arthroplasty as the previously cleared OrthAlign Plus® System (K162962). The Harvey Surgical Assistant is not indicated for total hip arthroplasty.

The Indications for Use are as follows:

Harvey Surgical Assistant System:

The Harvey Surgical Assistant 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 Harvey Surgical Assistant System facilitates the accurate positioning of implants, relative to these alignment axes.

Example orthopedic surgical procedures include but are not limited to:

- Total Knee Arthroplasty
- Unicompartmental Knee Arthroplasty: Tibial transverse resection

TECHNICAL CHARACTERISTICS COMPARED TO LEGALLY MARKETED DEVICE

The OrthAlign Plus® System was cleared to market under K162962. The OrthAlign Plus® System comprises a single use computer module, a reusable reference sensor and various surgical instruments. The devices uses algorithms to convert sensor outputs into spatial coordinates, providing graphical and numerical representation of instruments and anatomy on the user display screen.

The Harvey® Surgical Assistant System update the OrthAlign Plus® System:

- Operating System updated to a customized Android 7 operating system
- Single use computer module and reusable reference sensor housing material are revised

PERFORMANCE DATA

Device performance testing confirms that the Harvey® Surgical Assistant system can be used according to its intended use. The Harvey® Surgical Assistant system has been verified and validated according to OrthAlign's procedures for product design and development. Performance testing addressed the 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.
- Biocompatibility testing of revised materials

This testing regime demonstrates that the modified device is as safe, as effective, and performs as well as the existing device. This testing regime demonstrates that the subject device is substantially equivalent to the legally marketed predicate device, for its intended use.

The information provided by OrthAlign in this 510(k) premarket notification confirms that the modified OrthAlign Harvey® Surgical Assistant system is substantially equivalent to the legally marked predicate device, the OrthAlign Plus® System (K162962).

BASIS FOR DETERMINING SUBSTANTIAL EQUIVALENCE

A technological comparison and bench testing demonstrate the substantial equivalence of the Harvey® Surgical Assistant System to the legally marketed OrthAlign Plus® System.

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

- The subject device software is modified to operate on an Android 7 operating system.
- The housing material for the Harvey unit and the Harvey reference sensor have been modified.