October 3, 2024

OrthAlign, Inc
Karyl Haskell
Vice President, Regulatory Affairs and Quality Assurance
153 Technology
Irvine, California 92618

Re: K242616
Trade/Device Name: Lantern® Hip
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: ONN
Dated: August 30, 2024
Received: September 3, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242616

Device Name
Lantern® Hip

Indications for Use *(Describe)*
Lantern® Hip 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. Lantern® Hip facilitates the accurate positioning of implants relative to these alignment axes. The system aids the surgeon in controlling leg length and offset discrepancies.

The Lantern® Hip is indicated for Total Hip Arthroplasty with an anterior hip approach (Direct Anterior Approach) and the patient in the supine position.

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.

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"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:	30 September 2024
APPLICANT	OrthAlign, Inc. 153 Technology Irvine CA 92618 Tel: (949) 715-2424 Fax: (949) 831-9500
OFFICIAL CORRESONDENT	Karyl Haskell Vice President of Regulatory Affairs and Quality Assurance 153 Technology Irvine CA 92618 Tel: (949) 715-2424 Fax: (949) 831-9500
DEVICE CLASSIFICATION	Class II, 21 CFR 882.4560
PRODUCT CODES	ONN: Intraoperative Orthopedic Joint Assessment Aid
DEVICE TRADE NAME	Lantern® Hip
PRIMARY PREDICATE DEVICE	OrthAlign Plus System (K171780)
Reference Device	Harvey® Surgical Assistant (K200892)
SUBMISSION TYPE	Special 510(k) device modification. The subject device is a modification to the legally marketed OrthAlign Plus® System (K171780)

SUBSTANTIALLY EQUIVALENCE

The Lantern® Hip is substantially equivalent to the legally marketed OrthAlign Plus® System(K171780).

DEVICE DESCRIPTION

The Lantern® Hip (modified device) 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 Lantern® Hip 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. Lantern® Hip facilitates the accurate positioning of implants relative to these alignment axes. The system aids the surgeon in controlling leg length and offset discrepancies

The Lantern® Hip consists of the sterile, single-use Lantern® Hip navigation unit (packaging includes reference sensor, CR2 battery and femur sensor battery), the non-sterile reusable reference

sensor, the non-sterile reusable femur sensor, and associated non-sterile reusable instrumentation. The Lantern® Hip unit is sterile unless the sterile packaging is opened or damaged.

INDICATIONS FOR USE

The Lantern® Hip has the same hip arthroplasty (Direct Anterior Approach with the patient in a supine position) indication as the legally marketed OrthAlign Plus® System (K171780). The Lantern® Hip is not indicated for lateral hip arthroplasty and is not indicated for knee arthroplasty.

Lantern® Hip 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. Lantern® Hip facilitates the accurate positioning of implants relative to these alignment axes. The system aids the surgeon in controlling leg length and offset discrepancies.

The Lantern® Hip is indicated for Total Hip Arthroplasty with an anterior hip approach (Direct Anterior Approach) and the patient in the supine position.

TECHNICAL CHARACTERISTICS COMPARED TO LEGALLY MARKETED DEVICE

The OrthAlign Plus® System was cleared to market under K171780. The OrthAlign Plus® System comprises a single use computer module, a reusable reference sensor and various surgical instruments. The devices use algorithms to convert sensor outputs into spatial coordinates, providing graphical and numerical representation of instruments and anatomy on the user display screen.

The Lantern® Hip 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 Lantern® Hip can be used according to its intended use. The Lantern® Hip 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 Lantern® Hip is substantially equivalent to the legally marked predicate device, the OrthAlign Plus® System (K171780).

BASIS FOR DETERMINING SUBSTANTIAL EQUIVALENCE

A technological comparison and bench testing demonstrate the substantial equivalence of the Lantern® Hip to the legally marketed OrthAlign Plus® System. The modified device is identical to the predicate OrthAlign Plus® System (K171780), with the following exceptions:

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