July 31, 2026

Orthalign, Inc.
Michaela Lindemann
Sr. Regulatory Affairs Specialist
153 Technology
Irvine, California 92618

Re: K262253
Trade/Device Name: Lantern Knee Navigation Unit (406000-03);Lantern Hip Navigation Unit (502000-03)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: ONN
Dated: July 1, 2026
Received: July 2, 2026

Dear Michaela Lindemann:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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)*
K262253

Device Name
Lantern Knee Navigation Unit (406000-03);Lantern Hip Navigation Unit (502000-03)

Indications for Use *(Describe)*

Lantern Knee Indications for Use:
The Lantern Knee 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 Lantern Knee facilitates the accurate positioning of implants relative to these alignment axes. Ligament balancing is provided by Lantern Knee in primary or revision Total Knee Arthroplasty.
Example orthopedic surgical procedures include but are not limited to:
• Total Knee Arthroplasty
• Unicompartmental Knee Arthroplasty: Tibial transverse resection
• Ligament Balancing

Lantern Hip Indications for use:
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. Lantern Hip is indicated for Total Hip Arthroplasty with the Direct Anterior Approach and the patient in the supine position, or through a posterior-based approach with the patient in the lateral position. Note, offset is only available with the Direct Anterior Approach.

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.

510(k) #: K262253

510(k) Summary

Prepared on: 2026-07-29

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	OrthAlign, Inc.
Applicant Address	153 Technology Irvine CA 92618 United States
Applicant Contact Telephone	7632226720
Applicant Contact	Ms. Michaela Lindemann
Applicant Contact Email	mlindemann@orthalign.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Lantern Knee Navigation Unit (406000-03); Lantern Hip Navigation Unit (502000-03)
Common Name	Stereotaxic instrument
Classification Name	Intraoperative Orthopedic Joint Assessment Aid
Regulation Number	882.4560
Product Code(s)	ONN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K200892	Lantern Surgical Assistant	OLO
K242616	Lantern Hip	ONN
K140331	OrthAlign Plus	OLO

Device Description Summary

21 CFR 807.92(a)(4)

The Lantern system utilizes a palm sized computer module and sensor(s) to generate positional information in orthopedic procedures, providing a sequence of steps for registration of anatomical landmarks, calculation of mechanical axes and references frames, and relative positioning of instruments.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Lantern Knee Indications for Use:
The Lantern Knee 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 Lantern Knee facilitates the accurate positioning of implants relative to these alignment axes. Ligament balancing is provided by Lantern Knee in primary or revision Total Knee Arthroplasty.
Example orthopedic surgical procedures include but are not limited to:
• Total Knee Arthroplasty
• Unicompartmental Knee Arthroplasty: Tibial transverse resection
• Ligament Balancing
Lantern Hip Indications for use:
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. Lantern Hip is indicated for Total Hip Arthroplasty with the Direct Anterior Approach and the patient in the supine position, or through a posterior-based approach with the patient in the lateral position. Note, offset is only available with the Direct Anterior Approach.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use for modified Lantern Knee device contains the following changes from the indications for use cleared in the predicate 510(k) (K200892): Lantern Surgical Assistant (K200892). "Lantern Surgical Assistant" was replaced with Lantern Knee in the modified indications for use submitted in this premarket notification. The modified Lantern Knee indications for use also includes the addition of the statement "Ligament balancing is provided by Lantern Knee in primary or revision Total Knee Arthroplasty". Ligament balancing was added to the Lantern Surgical Assistant System through a document to file to K200892.

The indications for use for the modified Lantern Hip device have been modified from the predicate Lantern Hip (K242616) in the following way:
The statement "or through a posterior based approach with the patient in the lateral position. Note offset is only available with the direct Anterior Approach" has been added to the modified Lantern Hip indications for use. The posterior based approach with the patient in the lateral position was added to the Lantern Hip System through a letter to file to K242616. The posterior based approach does not include offset.

Technological Comparison 21 CFR 807.92(a)(6)

The following technological characteristics are identical between the modified Lantern Knee and Lantern Hip Systems and the predicate Lantern Surgical Assistant System (K200892), and/or the predicate Lantern Hip System(K242616).
-Control Mechanism (identical to predicate devices)
-Operating Principals (identical to predicate devices
-Registration of Anatomy (identical to predicate devices)
-Measurement and Navigation (identical to predicate devices)
-Main System Components (identical to predicate devices)
-Energy Type (identical to predicate devices)
-Sterilization (identical to predicate devices)
-Patient interface (identical to predicate devices)
-Storage and Transportation Conditions (identical to K242616)
The following technological characteristics differ for the OrthAlign predicates:
-Materials: Replacement of the existing Enclosure Front Frame and Display module with an integrated Front-Frame Display on the modified device resulted in different patient-facing materials compared to the predicate devices. The new materials have been verified per FDA recognized consensus standards for Biocompatibility.
-User interface: The Lantern Hip workflow has been updated from what was cleared in K242616 to remove the greater trochanter workflow and add the lateral workflow. Both change were evaluated through the FDA Guidance Documents, “Deciding When to Submit a 510(k)for a Change to an Existing Device” and “Deciding When to Submit a 510(k) for a Software Change to an Existing Device and documented to the OrthAlign file for K242616.

K200892 was submitted to the Agency with the name Harvey® Surgical Assistant (HSA). OrthAlign has modified the marketing name to the Lantern® System. This modification does not imply any marketing claims. Throughout this premarket notification the terms Harvey or HSA are interchangeable with Lantern, Lantern System, or Lantern Surgical Assistant (LSA).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Clinical testing is not applicable

Non clinical testing included:
-System components biocompatibility assessment per ISO 10993-1 (2018)
  -ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-12, ISO 10993-23
-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 device meets its functional requirements
  -ISO 14971
-Mechanical verification to ensure outer shell mechanical integrity(drop testing) and user interface and visual references/features (housing translucency testing)
-EMC verification and validation
  -IEC/EN 61000-4-2, IEC/EN 61000-4-3, IEC/EN 61000-4-8. IEC 61000-4-39, CISPR 11/EN55011, CISPR 32/EN55032, IEC 60601-1, IEC 60601-1-2, and ANSI C63.27

-Electrical Safety verification and validation
  -IEC 60601-1, IEC 60601-1-6, and IEC 62304
-Accelerated Aging
  -ASMR F1980
-Distribution verification and validation
  -ASTM D4169, ISTA 3A, ASTM F88/F88M, ASTM F2096
Battery Verification
  -IEC 60086-4, IEC 60086-5
Sterilization assessment
  -AAMI/ISO TIR 28:2016 (R2024) Annex A

This testing regime demonstrates that the subject device is safe and performs as well as the predicate devices.

The Lantern System has been verified to meet the design input requirements and has been shown to be substantially equivalent to the predicate devices.