June 2, 2026

Orthalign, Inc.
Michaela Lindemann
Regulatory Affairs Specialist
153 Technology
Irvine, California 92608

Re: K253507
Trade/Device Name: Packaged Assembly, Reusable Navigation Unit; Lantern ASC, Smart Pack kit, Knee
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: ONN
Dated: April 30, 2026
Received: April 30, 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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K253507 |

Please provide the device trade name(s).

Packaged Assembly, Reusable Navigation Unit;
Lantern ASC, Smart Pack kit, Knee

Please provide your Indications for Use below.

The Lantern® ASC 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 Lantern® ASC system facilitates the accurate positioning of implants relative to these alignment axes. Ligament balancing is provided by the Lantern® ASC system 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

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use (21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K253507

# 510(k) Summary

Prepared on: 2026-05-29

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | OrthAlign, Inc. |
| Applicant Address | 153 Technology Irvine CA 92608 United States |
| Applicant Contact Telephone | 7632226720 |
| Applicant Contact | Ms. Michaela Lindemann |
| Applicant Contact Email | oaregulatory@orthalign.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Packaged Assembly, Reusable Navigation Unit; Lantern ASC, Smart Pack kit, Knee |
| 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 Knee (previously branded as Harvey(R) Surgical Assistant) | OLO |
| K243387 | Gyder Hip System | OLO |
| K242616 | Lantern(R) Hip (reference device) | ONN |

## Device Description Summary

21 CFR 807.92(a)(4)

The Lantern ASC 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 reference frames, relative positioning of instruments.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Lantern® ASC 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 Lantern® ASC system facilitates the accurate positioning of implants relative to these alignment axes. Ligament balancing is provided by the Lantern® ASC system 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

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device has Identical intended use as the predicate devices: Intended to assist the surgeon in determining reference alignment axes in relation to anatomical and instrumentation structures during stereotactic orthopedic surgical procedures. The systems facilitate the accurate positioning of implants relative to these alignment axes.

The indications for use of the subject device are identical to the OrthAlign predicate (Lantern Surgical Assistant Knee, K200892) with the addition of Ligament Balancing cleared in the OrthAlign reference device (Lantern(R) Hip, K242616). The predicate Gyder Surgical Hip device is indicated for use in total hip arthroplasty (Anterior) with acetabular cups that are uncemented and allow for post impaction measurement and confirmatory measurement. The difference in the subject device indications for use and the Gyder Surgical Hip predicate device does not change the intended use of the device and does not affect the safety and effectiveness of the subject device, when used as labeled.

## Technological Comparison 21 CFR 807.92(a)(6)

The following technological characteristics are identical between the modified device, the OrthAlign predicate device and/or the Gyder Surgical Hip System (K243387):
-Intended Use [Identical to OrthAlign predicate K200892 and Gyder Surgical K243387]
-Indications for Use [Identical to OrthAlign predicate K200892 and reference devices]
-Computer generation of positional information [identical to predicate devices]
-Registration of anatomy [identical to predicate devices]
-Surgical Workflow [identical to predicate devices]
-User Interface [identical to predicate devices]
-Energy Type [Identical to predicate devices]
-Patient Interface [Identical to OrthAlign predicate]
-Environmental Specifications [identical to predicate devices]
- Main System Components
Sterile Cover, Sterile transfer tool and non-sterile reusable navigation unit [identical to Gyder Surgical Predicate]. The OrthAlign predicate device is a sterile, single use device and therefore does not include a sterile cover nor sterile transfer tool.
Reference Sensor and surgical instruments [identical to OrthAlign Predicate]
- Sterilization EtO of sterile transfer tool/sterile cover [Identical to Gyder Surgical Predicate]
The following technological characteristics are substantially equivalent:
-Materials-The differences in materials have been verified per the same performance testing as the OrthAlign predicate.
-Biocompatability- Differences in patient facing materials have been verified per FDA recognized consensus standards for Biocompatibility.

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

Non clinical testing included:
-Software verification and validation to ensure th 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
-Cleaning, sterilization and shipping validations for the specified processes
  -AAMI TIR28, AAMI TIR12, AAMI ST98, ASTM D4169, ASTM F2096, ASTM F88/F88M, ISO 10993-7, ISO 11135, ISO 11737, ISO 11607, ISTA 3A
-System components biocompatbility assessment per ISO 10993-1 (2018)
  -ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-12, ISO 10993-21
-System accuracy testing by bench testing for angle measurement accuracy
  -ISO 13845
-System usability testing for formative and summative testing
  -IEC 62366
- Cybersecurity testing
  - ANSI AAMI SW96:2023
  - IEC 81001-5-1 ed 1.0 2021-12
- Cleaning and Disinfection of the navigation unit
  - ANSI AAMI ST98:2020
  - AAMI TIR 12:2020
- Transfer Validation of transfer of navigation unit into the sterile cover
This testing regime demonstrates that the subject device is safe and performs as well as the predicate devices.

Clinical testing is not Applicable

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