July 1, 2026

Ortoma AB
% John Smith
Partner
Hogan Lovells US Llp
Columbia Sq.
555 Thirteenth St., NW
Washington, District of Columbia 20004

Re: K261852
Trade/Device Name: OTS Hip
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 3, 2026
Received: June 3, 2026

Dear John Smith:

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,

Tejen D. Soni -S

For
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.	K261852

Please provide the device trade name(s).

OTS Hip

Please provide your Indications for Use below.

OTS Hip is indicated to enable planning of orthopedic surgical procedures based on CT and X-Ray medical imaging data of the patient anatomy. It is an intraoperative image-guided localization system that enables navigated surgery. It links a freehand probe, tracked by a passive marker sensor system, to virtual computer image space on a patient's preoperative image data being processed by the OTS platform.

The system is indicated for orthopedic hip surgical procedures where a reference to a rigid anatomical structure, such as the pelvis, can be identified relative to a system generated model of the anatomy. The system aids the surgeon to accurately navigate a compatible prosthesis to the preoperatively planned position.

The system is designed for orthopedic surgical procedures including:

- Pre-operative planning of total hip arthroplasty (THA)
- Intraoperative navigated surgery for THA using a posterior approach

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)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

Special 510(k) SUMMARY K261852

Ortoma AB OTS Hip

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Date Prepared: June 30, 2026

Name of Device: OTS Hip
Common or Usual Name: Stereotaxic Instrument

Classification Name: 21 CFR Section 882.4560, Stereotaxic Instrument
Regulatory Class: II
Product Code: OLO
Predicate Devices
Ortoma AB, OTS Hip (K250086)

Device Description

OTS Hip is a system to support a surgeon with preoperative planning and intraoperative guidance during orthopedic hip joint replacement surgery.

The OTS Hip device is a modified device from the company's previously cleared OTS Hip (K250086).

OTS Hip is comprised of software systems and hardware components that work together to form a stereotaxic system. The system uses medical imaging data in DICOM format that is loaded into the system for access in the software that are part of the system.

OTS Hip software consists of OTS Hip Plan (OHP), which is a 3D preoperative planning software, and OTS Hip Guide (OHG) that provides intraoperative real-time navigation for the guidance of surgical tools and prosthetic components in relation to the preoperatively determined goal positions.

OHP is a software for preoperative planning prior to a THA (Total Hip Arthroplasty) surgery. OHP enables the orthopedic surgeon to prepare surgery by analyzing the patient anatomy in a 3D environment based on medical imaging data.

OHG imports the result from the preceding planning stage, a released plan, with the 3D model and planned data, from the database of the OTS system. In addition, OHG monitors the real-time information of the position of instruments and prosthetic components in a 3D environment by means of medical imaging data.

The components of the OHG device include a camera and computer stand with an electrical system to which a camera and a medical panel PC are attached, a footswitch, a keyboard, Tracers (passive markers), adapters that hold the Tracers and can be mounted to compatible surgical instruments and that are used for calibration, and tools and instruments that are used during surgery.

The OTS Hip is compatible with the following components:

- PINN GB OFFSET GRATER HANDLE, DePuy Synthes 2550-00-100
- EMPHASYS Offset reamer, DePuy Synthes 4811-00-510
- Greatbatch Offset Cup Impactor, DePuy Synthes 2550-00-115
- PINNACLE straight impactor, DePuy Synthes 2217-50-041
- EMPHASYS Straight impactor, DePuy Synthes 4812-01-150
- KINCISE™ PINNACLE Straight Shell Impactor, DePuy Synthes 2000-02-002 (long)
- KINCISE™ PINNACLE Straight Shell Impactor, DePuy Synthes 2000-02-012 (short)
- KINCISE™ EMPHASYS Straight Shell Impactor, DePuy Synthes 2000-03-001 (long)
- KINCISE™ EMPHASYS Straight Shell Impactor, DePuy Synthes 2000-03-012 (short)
- KINCISE™ EMPHASYS Offset Shell Impactor, DePuy Synthes 2000-03-002
- KINCISE™ PINNACLE Offset Shell Impactor, DePuy Synthes 2000-02-003
- Crossback Acetabular Reamer Head, DePuy Synthes, 2550-00-0XX (Size 36mm to 80mm)
- QUICKSET Acetabular Grater Head, DePuy Synthes 2440-00-5XX (Size 36mm to 80mm)

Indications for Use

OTS Hip is indicated to enable planning of orthopedic surgical procedures based on CT and X-Ray medical imaging data of the patient anatomy. It is an intraoperative image-guided localization system that enables navigated surgery. It links a freehand probe, tracked by a passive marker sensor system, to virtual computer image space on a patient's preoperative image data being processed by the OTS platform.

The system is indicated for orthopedic hip surgical procedures where a reference to a rigid anatomical structure, such as the pelvis, can be identified relative to a system generated model of the anatomy. The system aids the surgeon to accurately navigate a compatible prosthesis to the preoperatively planned position.

The system is designed for orthopedic surgical procedures including:

- Pre-operative planning of total hip arthroplasty (THA)

- Intraoperative navigated surgery for THA using a posterior approach

Additional Considerations for Use

The device should not be used for patients with implants in the treatment side.

Summary of Technological Characteristics

Both the predicate device and the subject device enable pre-operative planning and navigation of prosthetic components. OTS Hip is comprised of software systems and hardware components that work together to form a stereotaxic system.

Like the predicate device, the subject device includes software for pre-operative planning of orthopedic prosthetic components. The predicate device and the subject device have the same workflow for anatomical landmarks and planning of implant size and positions. Both devices detect landmarks and perform segmentation using fixed/static machine learning (ML) algorithms and generate a 3D model based on the segmentation.

Like the predicate device, the subject device enables intraoperative image-guided navigated surgery using the OHG software and hardware components. The subject device and the predicate device include hardware components and a software for real-time navigation of surgical instruments and implants relative to the patient. Both devices use similar tracking arrays (tracers). The software included in OHG of the subject device and the predicate device is workflow based, where the user is guided to perform various steps in the workflow.

The OTS Hip updates include minor hardware and instrument changes, as well as expanded compatibility with KINCISE™ Offset shell impactors and QUICKSET™ reamer heads. Across the OTS

software modules, updates consist of incremental user interface and logging enhancements, ongoing software maintenance, bug fixes, security updates, labeling updates, and limited functional improvements.

The performance testing demonstrates that the performance characteristics of the OTS Hip are equivalent to those of the predicate device and therefore supports a determination of Substantial Equivalence for the proposed indications for use.

Differences between the subject and predicate device do not impact or affect the safety or effectiveness of the device or raise different questions of safety and effectiveness.

Performance Testing

To support the changes to OTS Hip, the following performance testing has been completed for the subject device in support of the substantial equivalence decision:

- Mechanical robustness testing:
  Simulated surgical-use testing (including repeated impaction and reaming scenarios) was performed to confirm structural integrity, durability, and maintenance of calibration accuracy. All tests met predefined acceptance criteria.

- Compatibility validation with new instruments:
  Integration and functional compatibility were verified through simulated use and system-level testing to ensure correct performance, calibration stability, and safe interaction with newly supported instruments.

- Electrical and mechanical safety of system updates:

  IEC 60601-1 testing (including stability, mechanical transport, electrical safety, leakage current, and grounding) was conducted with all requirements successfully met.

- Software verification and validation

  Software V&V activities were executed in accordance with IEC 62304. All results were as expected.

Substantial Equivalence Comparison

Characteristic	OTS Hip - Subject Device	OTS Hip - Predicate Device	Equivalence Assessment
510(k) Number	K261852	K250086	N/A
Manufacturer	Ortoma AB	Ortoma AB	N/A
Regulation	21 CFR 882.4560	21 CFR 882.4560	Same
Product Code	OLO	OLO	Same
Intended Use	To enable planning of orthopedic surgical procedures and enable intraoperative image-guided surgery.	To enable planning of orthopedic surgical procedures and enable intraoperative image-guided surgery.	Same
Indications for Use	OTS Hip is indicated to enable planning of orthopedic surgical procedures based on CT and X-Ray medical imaging data of the patient anatomy. It is an intraoperative image-guided localization system that enables navigated surgery. It links a freehand probe, tracked by a passive marker sensor system, to virtual computer image space on a patient's preoperative image data being processed by the OTS platform. The system is indicated for orthopedic hip surgical procedures where a reference to a rigid anatomical structure, such as the pelvis, can be identified relative to a system generated model of the anatomy. The system aids the surgeon to accurately navigate a compatible prosthesis to the preoperatively planned position.	OTS Hip is indicated to enable planning of orthopedic surgical procedures based on CT and X-Ray medical imaging data of the patient anatomy. It is an intraoperative image-guided localization system that enables navigated surgery. It links a freehand probe, tracked by a passive marker sensor system, to virtual computer image space on a patient's preoperative image data being processed by the OTS platform. The system is indicated for orthopedic hip surgical procedures where a reference to a rigid anatomical structure, such as the pelvis, can be identified relative to a system generated model of the anatomy. The system aids the surgeon to accurately navigate a compatible prosthesis to the preoperatively planned position.	Same

Characteristic	OTS Hip - Subject Device	OTS Hip - Predicate Device	Equivalence Assessment
	The system is designed for orthopedic surgical procedures including: • Pre-operative planning of Total Hip Arthroplasty (THA) • Intraoperative navigated surgery for THA using a posterior approach	The system is designed for orthopedic surgical procedures including: • Pre-operative planning of Total Hip Arthroplasty (THA) • Intraoperative navigated surgery for THA using a posterior approach •	
User Population	Orthopedic surgeon	Orthopedic surgeon	Same
Anatomical Site	Hip	Hip	Same
Where Used	Office of user and Operating room	Office of user and Operating room	Same
Technological Principle of Operation	Intraoperative image-guided localization system allowing user to plan surgery using premeasurements of patient anatomy. Software tracks anatomy, implants and surgical tools in real-time.	Intraoperative image-guided localization system allowing user to plan surgery using premeasurements of patient anatomy. Software tracks anatomy, implants and surgical tools in real-time.	Same
Main Technology of MIS	The technology of Minimally Invasive Surgery (MIS) is based on Image Guided Surgery (IGS) devices.	The technology of Minimally Invasive Surgery (MIS) is based on Image Guided Surgery (IGS) devices.	Same
Principle of Operation Flow	Preoperative image > surgical planning > surgical guiding > recording	Preoperative image > surgical planning > surgical guiding > recording	Same
Major Components	Software for planning and guiding Minor SW updates and bug fixes	Software for planning and guiding	Similar
	Calibration Adapter Unit OTD	Calibration Adapter Unit OTD	Same
	Calibration Adapter Unit OTD	Calibration Adapter Unit OTD Emphasys	Same
	Inserter Adapter OTD – design and manufacturing	Inserter Adapter OTD	Similar

Characteristic	OTS Hip - Subject Device	OTS Hip - Predicate Device	Equivalence Assessment
	to multiple milled sub-components		
	Reamer Adapter OTD – design and manufacturing to multiple milled sub-components	Reamer Adapter OTD	Similar
	Inserter Adapter OTD Straight - design and manufacturing to multiple milled sub-components	Inserter Adapter OTD Straight	Similar
	Inserter Adapter OTD Pinnacle Straight design and manufacturing to multiple milled sub-components	Inserter Adapter OTD Pinnacle Straight	Similar
	Attachment Adapter Fix OT	Attachment Adapter Fix OT	Same
	Attachment Adapter Twin OT	Attachment Adapter Twin OT	Same
	Stylet & Pin	Stylet & Pin	Same
	Pointer OT	Pointer OT	Same
	Pointer Holder	Pointer Holder	Same
	Tracers	Tracers	Same
	OTS Instrumentation – minor design change to threaded shaft of measurement screw driver	OTS Instrumentation	Similar
	Camera (NDI)	Camera (NDI)	Same
	Computer (Baaske, e-medic Silence TP2)	Computer (Baaske, e-medic Silence TP2)	Same
	Computer and Camera Stand (with integrated Power inlet and MSO (Jansen Medicars, Flexx one 2G 180 - Ortoma, 3012.00.00.071)) Small dimension update of chart	Computer and Camera Stand (with integrated Power inlet and MSO (Jansen Medicars, Flexx one 2G 180 - Ortoma, 3012.00.00.071))	Same

Characteristic	OTS Hip - Subject Device	OTS Hip - Predicate Device	Equivalence Assessment
	Keyboard (ProKeys e.K., K10 MED Compact-LS-USB-US/JP)	Keyboard (ProKeys e.K., K10 MED Compact-LS-USB-US/JP)	Same
	Footswitch (Herga, MD3G-DGA-GZ1-AAA-001)	Footswitch (Herga, MD3G-DGA-GZ1-AAA-001)	Same
Tracking/ Navigation Technology	Real-time Optical Tracking System (OPS)	Real-time Optical Tracking System (OPS)	Same
Input Image Planning	Computer Tomography (CT), X-Ray	Computer Tomography (CT), X-Ray	Same
Input Image Guiding	3D image of the unique patient´s anatomy	3D image of the unique patient´s anatomy	Same
DICOM compliance	Yes	Yes	Same
Save/load planning	Yes	Yes	Same
Accessories	None	None	Same
Power Source	Mains	Mains	Same
Biocompatibility	Tested per ISO 10993	Tested per ISO 10993	Same
Software	SW application for pre-operative planning and navigation Minor SW updates and bug fixes	SW application for pre-operative planning and navigation	Similar
Sterilization	Steam sterilization for reusable components Gamma sterilization for single use components	Steam sterilization for reusable components Gamma sterilization for single use components	Same

Conclusions

The OTS Hip is as safe and effective as the Ortoma Treatment Solution system (K250086). The OTS Hip has the same intended use and indications for use, similar technological characteristics, and principles of operation as its predicate device. The minor differences in the indications do not alter the intended therapeutic use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the OTS Hip and the predicate OTS Hip device raise no new issues of safety or effectiveness. Performance data demonstrate that the OTS Hip is as safe and effective as the predicate OTS Hip (K250086). Thus, the OTS Hip (K261852) is substantially equivalent.