



May 16, 2025

Ortoma AB
% John Smith
Partner
Hogan Lovells, LLC
Columbia Square, 555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K250086
Trade/Device Name: OTS Hip
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 13, 2025
Received: April 17, 2025

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 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

Indications for Use

510(k) Number (if known)

K250086

Device Name

OTS Hip

Indications for Use (Describe)

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

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.

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510(k) SUMMARY
Ortoma AB OTS Hip
K250086

Submitter

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Date Prepared: May 13, 2025

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 (K232140)

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 (K232140).

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 4812-00-150
- 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)

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.

The changes include pre-processing and additional use of x-ray medical imaging data. The proposed device includes a customer specific configuration that utilizes both standing and flexed seated x-rays during a pre-operative plan. The configuration provides initial cup angles for planning that are patient specific. The user shall always review and approve the values to be exported to OTS Hip (OTS Hip Guide SW). The customer specific configuration includes an algorithm component previously cleared in K231503.

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.

OTS Hip includes additional minor changes to hardware components and additional compatibility with tools for Kincise Surgical Automated System Components.

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

The following performance testing has been completed for the subject device, in support of the substantial equivalence decision:

Quantitative System Level Validation

Quantitative system level validation testing was performed using data collected from human cadaver studies enabling validation of system level accuracy and specific functionality within the system.

The results demonstrated that the inclination, anteversion, the mean deviation for position error, and leg length inequality were equivalent to results obtained for the predicate device.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC assessment demonstrates conformance to IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION and IEC 60601-1-2:2014 [Including AMD 1:2021].

Machine Learning Algorithm Validation

CT Algorithm Segmentation and Landmark Validation

Validation testing demonstrated the accuracy of Machine Learning (ML) algorithms for segmentation and landmark identification.

The results of segmentation and landmark ML algorithms were compared with the manually annotated “ground truth” segmentations and landmarks of the test dataset. Appropriately qualified clinical experts established the ground truth. Using objective criteria, cases were evaluated by blinded annotators. Cases were then separated into training and testing datasets in an unbiased fashion. Cases assigned to the test dataset were then validated by a third reviewer who was not included in the annotation process of the training data.

The test datasets consisted of 90 datasets from both US and OUS data which were representative of the US population in terms of gender, age, and ethnicity and included images from multiple CT equipment manufacturers.

The dataset consisted of patients from the US (45.6%), Japan (33.3%), and the European Union (21.1%). Notably, the data from Japan included a high percentage of dysplastic hips with accompanying marked degenerative change representing a worst case scenario for the intended US intended use population.

The OUS dataset was unblinded.

For the OUS datasets, independent datasets were used between training and testing, though the two datasets were collected from the same site.

Subgroup analyses were conducted based on data variables such as scanner manufacture, slice thickness and imaging parameters. The test datasets were independent from the training dataset, where none of the datasets used for training was used for testing.

The ML-models overall met the acceptance criteria.

Sacral Slope Landmark Identification Algorithm Validation

Validation testing demonstrated the accuracy of Machine Learning (ML) algorithms for Sacral Slope landmark added for x-ray images.

The results of the Sacral Slope landmark ML algorithm were compared with the manually annotated “ground truth” landmarks of the test dataset. Appropriately qualified clinical experts established the ground truth. Using objective criteria, cases were evaluated by blinded annotators. Cases were then separated into training and testing datasets in an unbiased fashion. Cases assigned to the test dataset were then validated by a third reviewer who was not included in the annotation process of the training data.

The test datasets consisted of 503 x-ray images from 276 US patients which were representative of the US population in terms of gender, age, and ethnicity and included images from multiple x-ray equipment manufacturers.

Subgroup analyses were conducted based on patient covariates and data acquisition covariates such as scanner type, x-ray tube current and imaging parameters. The test datasets were independent from the training dataset, where none of the x-ray images or patients included in the training dataset were re-used in the test dataset.

The ML-model met the acceptance criteria.

Design Verification

The following design verification activities have been performed to ensure the correct functionality of the system as it has been specified. Tests were successfully completed.

- Verifying the accuracy performance of the localization and tracking technology using the standardized test procedure according to ASTM Standard F2554-18.

- Functional testing to ensure that all functional requirements are fulfilled for new compatible systems and revised components.
- Safety testing verifying the effectiveness of all risk controls determined in the device risk analysis.
- Risk assessment was performed per ISO 14971:2019 Medical devices – Application or Risk Management to medical devices.
- A detailed verification was performed covering the detailed functionality of the software (e.g., calculations of measurements from CT scans and X-Ray images).

Non-clinical tests were performed to confirm the system targets. Specific OR setups and surgical procedures were simulated in laboratory environments and human cadaver labs.

Substantial Equivalence Comparison

Characteristic	OTS Hip – Subject Device	OTS Hip – Predicate Device	Equivalence Assessment
510(k) Number	TBD	K232140	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	OTS Hip is indicated to enable planning of orthopedic surgical procedures based on CT 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.	Similar

Characteristic	OTS Hip – Subject Device	OTS Hip – Predicate Device	Equivalence Assessment
	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	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 CT-based 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 and 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

Characteristic	OTS Hip – Subject Device	OTS Hip – Predicate Device	Equivalence Assessment
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 Functionality added for new configuration Minor SW updates and bug fixes	Software for planning and guiding	Similar
	Calibration Adapter Unit OTD with holes removed that are not needed.	Calibration Adapter Unit OTD	Similar
	Calibration Adapter Unit OTD Emphasys with holes removed that are not needed.	Calibration Adapter Unit OTD Emphasys	Similar
	Inserter Adapter OTD	Inserter Adapter OTD	Same
	Reamer Adapter OTD	Reamer Adapter OTD	Same
	Inserter Adapter OTD Straight - Improved interface toward tool and added compatibility for additional tools.	Inserter Adapter OTD Straight	Similar
	Inserter Adapter OTD Pinnacle Straight	Inserter Adapter OTD Pinnacle Straight	Same
	Attachment Adapter Fix OT	Attachment Adapter Fix OT	Same
	Attachment Adapter Twin OT - Minor design adjustment of pin hole position	Attachment Adapter Twin OT	Similar
	Stylet & Pin	Stylet & Pin	Same
	Pointer OT	Pointer OT	Same
	Pointer Holder	Pointer Holder	Same
	Tracers – minor change reflective tape	Tracers	Similar
	OTS Instrumentation – Improved interface towards the Threaded Pin	OTS Instrumentation	Similar

Characteristic	OTS Hip – Subject Device	OTS Hip – Predicate Device	Equivalence Assessment
	Camera (NDI)	Camera (NDI)	Same
	Computer (Baaske, e-medice Silence TP2)	Computer (Baaske, e-medice Silence TP2)	Same
	Computer and Camera Stand (with integrated Power inlet and MSO (Jansen Medicars, Flexx one 2G 180 - Ortoma, 3012.00.00.071)) The Computer and Camera Stand has been updated to add support for replacement of the cable.	Computer and Camera Stand (Jansen Medicars, Flexx one 180 – Ortoma, 3005.00.00.130)	Similar
	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 with extended pre-processing and additional use of x-ray medical imaging data.	Computer Tomography (CT), X-Ray	Similar
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 Functionality added for new Configuration	SW application for pre-operative planning and navigation	Similar

Characteristic	OTS Hip – Subject Device	OTS Hip – Predicate Device	Equivalence Assessment
	Minor SW updates and bug fixes		
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 (K232140). The OTS Hip has the same intended uses and similar indications, 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 (K232140). Thus, the OTS Hip is substantially equivalent.