March 11, 2024

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

Re: K232140
Trade/Device Name: OTS Hip
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: February 9, 2024
Received: February 9, 2024

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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232140

Device Name
OTS Hip

Indications for Use *(Describe)*
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.

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 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.

510(k) SUMMARY - K232140
Ortoma AB OTS Hip

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Date Prepared: March 11, 2024

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, Ortoma Treatment Solution system (K181449)

Device Description

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

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 is compatible with the following Depuy Synthes components:

- PINN GB OFFSET GRATER HANDLE, DePuy Synthes 255000100
- Emphasys offset reamer, DePuy Synthes 4811-00-510
- Greatbatch Offset Cup Impactor, DePuy Synthes 255000115
- Pinnacle straight impactor, DePuy Synthes 221750041
- Emphasys straight impactor, DePuy Synthes 4812-00-150

Intended Use / Indications for Use

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.

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 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, OTS Hip Plan (OHP). The predicate device and the subject device have the same workflow for anatomical landmarks, and planning of implant size and positions. In the subject device functionality is changed to detect landmarks and perform segmentation using fixed/static machine learning (ML) algorithms, and to 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. A disposable tracking array called Tracer in the subject device replaces the combination of Marker and Marker Reflector Disc in the predicate device. 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 subject device includes a new version of the computer and camera stand with electrical components. A computer has been added to the subject device the camera of the system has been changed to a camera from a new supplier. The underlying technology with infra-red tracking of passive markers remains the same as in the predicate device. In the subject device, a new version of the passive markers, called Tracers, has replaced the passive markers in the predicate device.

Components that are used in surgery include adapters, which are used to hold the passive markers. The adapters have the same function, to hold the passive marker relative to a compatible instrument, in the predicate device and the subject device. In the subject device, new adapters have been added with a revised design to hold the Tracer and to fit to compatible instruments that are supported by the subject device. Components, OTS Instruments that includes screws and drivers, have been added in the subject device, replacing components from external suppliers.

The OTS Hip has the equivalent indications for use and similar design features as compared with the predicate system.

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.

Any differences between the subject and predicate device would not render the device NSE, affect the safety or effectiveness, 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 real-life data from surgeries under clinical conditions enabling validation of system level accuracy and specific functionality within the system.

The results demonstrated that the inclination and anteversion, and the mean deviation for position error were acceptable for stereotactic systems.

Leg length measurements were evaluated for residual Leg Length Inequality (LLI) and was found to be within clinically acceptable values and would not affect the safety or effectiveness, or raise different questions of safety and effectiveness.

Electrical Safety and Electromagnetic Compatibility (EMC) Testing

Electrical safety and EMC testing demonstrates conformance to IEC 60601-1:2005 (3rd Ed) and IEC 60601-1-2:2014 (4th Ed).

Machine Learning Algorithm 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 evaluated the initial annotation.

For the segmentation validation, two clinically complex cases that would be difficult for clinicians to manually interpret did not pass the acceptance criteria. However, the ML-models overall met the acceptance criteria.

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.

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 thickens and imaging parameters. The test datasets were independent from the training dataset, where none of the datasets used for training was used for testing.

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.
- 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).

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

Substantial Equivalence Comparison

Characteristic	OTS Hip – Subject Device	Ortoma Treatment Solution – Predicate Device	Equivalence Assessment
510(k) Number	K232140	K181449	N/A

Manufacturer	Ortoma AB	Same	N/A
Regulation	21 CFR 882.4560	21 CFR 882.4560	Identical
Product Code	OLO	OLO	Identical
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.	Identical
Indications for Use	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. 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:	The Ortoma Treatment Solution system is intended to be an intraoperative image-guided localization system to enable navigated surgery. It links a freehand probe, tracked by a passive marker sensor system, to virtual computer image space either on a patient's preoperative image data being processed by OTS platform, or on an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface. The system is indicated for hip surgical procedures, in which the use of navigated surgery is considered to be safe and effective, and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT-based model of the anatomy. The system aids the surgeon to accurately navigate a hip prosthesis to the preoperatively planned position. Example orthopedic surgical procedures include but are not limited to:	Equivalent Revised indications do not affect the device's diagnostic or therapeutic effects.

	• Pre-operative planning and of Total Hip Arthroplasty (THA) • Intraoperative navigated surgery for THA using a posterior approach.	• Total Hip Arthroplasty (THA) using posterior approach. • Preoperative planning and intraoperative navigated surgery for joint replacement with Stryker Exeter X3 Rimfit cups.	
User Population	Orthopedic surgeon	Orthopedic surgeon	Identical
Anatomical Site	Hip	Hip	Identical
Where Used	Office of user and Operating room	Operating room	Substantially Equivalent. Support for pre-operative planning in the user office to support user standard working environment. Preoperative planning is not dependent on environment in operating room since input data is generated before entering the operating room.
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.	Identical

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.	Identical
Principle of Operation Flow	Preoperative image > surgical planning > surgical guiding > recording	Preoperative image > surgical planning > surgical guiding > recording	Identical
Major Components	Software for planning and guiding	Software for planning and guiding	Substantially Equivalent.
	Calibration Adapter Unit OTD	Calibration Adapter Unit	Substantially Equivalent. Updated version to support compatible implant system and new tracking array (Tracers).
	Calibration Adapter Unit OTD Emphasys	Calibration Adapter Unit	Substantially Equivalent. New version to support compatible implant system and new tracking array (Tracers).
	Inserter Adapter OTD	Inserter Adapter	Substantially Equivalent. Updated version to support compatible implant system and new tracking array (Tracers).
	Reamer Adapter OTD	Reamer Adapter	Substantially Equivalent. Updated version to support compatible implant system and new tracking array (Tracers).
	Inserter Adapter OTD Straight	Inserter Adapter	Substantially Equivalent. New version to support compatible implant system and new tracking array (Tracers).

	Inserter Adapter OTD Pinnacle Straight	Inserter Adapter	Substantially Equivalent. New variant to support compatible implant system and new tracking array (Tracers).
	Attachment Adapter Fix	Attachment Adapter for Stryker OrthoLock EX-Pin 4x150	Substantially Equivalent Updated version to support Ortoma supplied screws.
	Attachment Adapter Twin	Calibration Adapter Unit	Substantially Equivalent Added variant to support two points fixation.
	Stylet & Pin	Stylet & Pin	Identical
	Pointer	Pointer 1 Pointer 2 Pointer 3	Substantially Equivalent. Updated version to support new tracking array (Tracers).
	Pointer Holder	None	Different - Added component for support of leg length functionality. This difference is supported by adequate bench testing.
	Tracers	Markers Marker Reflector Disc Disc Inserter/ Remover Tool	Substantially Equivalent. Two components combined in one single component. No need of Tool to mount Marker Reflector Disc in Marker.
	OTS Instrumentation	External components	Substantially Equivalent. Components are not new but are now

			supplied by Ortoma rather than left to the user to procure.
	Camera (NDI)	Camera (Atracsys)	Substantially Equivalent. Same technology, different supplier.
	Computer (Baaske, e-medic Silence TP2)	Computer (supplied by user).	Substantially Equivalent. Component is now supplied by Ortoma rather than left to the user to procure.
	Computer and Camera Stand (Jansen Medicars, Flexx one 180 – Ortoma, 3005.00.00.130)	Computer and Camera stand	Substantially Equivalent. Updated version
	Keyboard (ProKeys e.K., K10 MED Compact-LS-USB-US/JP)	Keyboard (Supplied by user)	Substantially Equivalent. Component is now supplied by Ortoma rather than left to the user to procure.
	Footswitch (Herga, MD3G-DGA-GZ1-AAA-001)	Footswitch	Substantially Equivalent. Updated version
Tracking/ Navigation Technology	Real-time Optical Tracking System (OPS)	Real-time Optical Tracking System (OPS)	Identical
Input Image Planning	Computer Tomography (CT), X-Ray	Computer Tomography (CT)	Substantially Equivalent. Functionality added for X-Ray as optional input, and as support for planning (as a user reference only).
Input Image Guiding	3D image of the unique patient´s anatomy	3D image of the unique patient´s anatomy	Identical
DICOM compliance	Yes	Yes	Identical
Save/load planning	Yes	Yes	Identical
Accessories	None	None	Identical

Power Source	Mains	Mains	Identical
Biocompatibility	Tested per ISO 10993	Tested per ISO 10993	Identical
Software	SW application for pre-operative planning and navigation	SW application for pre-operative planning and navigation	Identical
Sterilization	Steam sterilization for reusable components Gamma sterilization for single use components	Steam sterilization for reusable components Gamma sterilization for single use components	Identical

Conclusions

The OTS Hip is as safe and effective as the Ortoma Treatment Solution system (K181449). 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 its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the OTS Hip is as safe and effective as the Ortoma Treatment Solution system (K181449). Thus, the OTS Hip is substantially equivalent.