Ortoma AB
% Jennifer Daudelin
Regulatory Consultant III
M Squared Associates, Inc.
575 Eighth Avenue
New York, New York 10018

Re: K181449
Trade/Device Name: Ortoma Treatment Solution - OTS
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 20, 2018
Received: June 21, 2018

Dear Jennifer Daudelin:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel S. Ramsey -S
2018.09.19 08:41:49 -04'00'

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181449

Device Name
Ortoma Treatment Solution (OTS)

Indications for Use *(Describe)*
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:
Total Hip Arthroplasty (THA) using posterior approach.
Preoperative planning and intraoperative navigated surgery for joint replacement with Stryker Exeter X3 Rimfit cups.

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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K181449

510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the Ortoma Treatment Solution (OTS) 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Sponsor: Ortoma AB
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Date Prepared: May 17, 2018

Proposed Class: II

Proprietary Name: Ortoma Treatment Solution – OTS

Common Name: Planning and Guiding Surgery System

Classification Name: Orthopedic, Stereotaxic Instrument

Regulation Number: 21 CFR 882.4560

Product Codes: OLO

Predicate Device(s):

Manufacturer	Device Name	510(k) Number	Procode	Class
Brainlab AG	Brainlab Hip	K122011	OLO	II

Indications for Use

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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.

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Example orthopedic surgical procedures include but are not limited to:

Total Hip Arthroplasty (THA) using posterior approach.
Preoperative planning and intraoperative navigated surgery for joint replacement with Stryker Exeter X3 Rimfit cups.

Device Description

The Ortoma Treatment Solution – OTS is a stereotactic navigation system, supporting the surgeon with positioning information in relation to the individual patient anatomy before and during orthopedic hip joint replacement surgery.
OTS consists of two software parts:

- Ortoma Hip Plan – OHP, a 3D preoperative planning application
- Ortoma Hip Guide – OHG, provides real-time navigation for guidance of surgical tools and prosthetic components in relation to the preoperatively determined goal position

OHP has support for PACS (Picture Archiving Communication System) solutions already available at Hospitals. The PACS system handles the DICOM (Digital Imaging and Communications in Medicine) data obtained from Computed Tomography (CT) scans of patients. DICOM data from the PACS system is uploaded into the OHP and an illustrative 3D image of the unique patient´s anatomy is created.

The OHP application includes functions to define the measurements of the individual patient anatomy, such as the offset, anteversion and leg length. The surgeon selects prosthetic components

in relation to the anatomy data and measurements obtained in the application, to virtually decide the position of the prosthetic components.

The OHG application functions as a positioning system in relation to the preoperatively planned goal position. The system includes passive retro-reflective markers with camera, monitor and adapters to attach the passive retro-reflective markers to surgical instruments. The OHG gives the surgeon real-time positioning information, while the orthopedic surgeon positions the surgical instruments and prosthetic components during the implant surgery, in relation to the patient anatomy as previously planned. The surgeons decide based on their clinical knowledge and experience how the surgery should be performed.

The OTS is compatible with the following Stryker components: Stryker Asnis III 4.0x20 mm full thread stainless steel, Stryker Holding Sleeve for Screwdrivers, Stryker Cannulated Screwdriver with AO Coupling – Hex 2.5mm, Stryker Ortholock Ex-Pin 150x4 mm screw, Stryker quick release apex, Stryker Reamer, and Stryker Cup Inserter.

Performance Data

The following performance data were provided in support of the substantial equivalence decision:

Quantitative System Level Validation

Quantitative system level validation testing under simulated clinical conditions was performed on four (4) consecutively selected human cadavers for a total of 8 hips. The human cadaver subjects ranged in age from 49 to 80 years old and were male. The human subjects were treated with THA using a posterior surgical approach according to the surgical technique for the Stryker Exeter X3 RimFit Acetabular Cup. As per the study protocol, the human subjects were CT scanned with a low dose CT protocol and then implanted with the Stryker Exeter X3 RimFit Acetabular Cup using the Ortoma OTS device. Results were obtained for 7 hips (one hip was excluded due to unacceptable bone in the acetabulum and surrounding bone for reliable navigation). The results showed the following deviation between the postoperative CT-scan reference data and the Ortoma Hip Guide results:

- Inclination: -0.30º ± 1.95º

- Anteversion: -0.26º ± 1.90º
- Distance: 1.45 ± 0.59 mm

These results demonstrated that the inclination and anteversion were not outside the safe zone of ± 10° as defined by Lewinnek et al. and that the mean deviation for distance of 1.45±0.59 mm, with the maximum deviation of 2.64 mm, is below the acceptable accuracy level of ±3mm for stereotactic systems.

This study also validated the single pin attachment method. The bias was about 0.5 mm or lower in seven of the surgeries and about 0.9 mm in one surgery. This sets an upper limit to the potential motion of the reference marker during the eight surgeries of 0.9 mm.

In summary, the accuracy validation of the inclination, anteversion, and distance are within the safe zone according to the gold standard (Lewinnek et al.). The accuracy deviation results demonstrate that the OTS device performs accurately under simulated clinical conditions. Moreover, the OTS system accuracy deviation results further confirm the rigidity of the single pin attachment method.

Electrical Safety and Electromagnetic Compatibility (EMC) Testing

Electrical safety and EMC testing according to IEC 60601-1:2005 (3rd Ed) and IEC 60601-1-2:2014 (4rd Ed) was conducted and test results provided. The device fulfills the requirements.

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 F2554-10.
- 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.
- Usability and Risk assessment was validated per following standards: IEC62366:2015 Medical devices – Application of usability engineering to medical devices and EN ISO 14971:2012 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.

Technological Characteristics and Substantial Equivalence

The Ortoma OTS system has the same indications for use and similar design features as compared with the predicate system. The cadaver study and bench testing demonstrate that the performance characteristics of the Ortoma OTS are equivalent to those of the other legally marketed stereotaxic instruments, and therefore supports a determination of Substantial Equivalence for the proposed indications for use.

The following technological differences exist between the subject and predicate devices:

- The subject OTS system uses marker discs for its tracking arrays while the predicate Brainlab Hip utilizes spheres for tracking arrays. Validation testing of the OTS marker discs demonstrated that the discs obtained the acceptable level of system accuracy for stereotaxic systems.
- The subject OTS system uses standard orthopedic instruments for implantation provided by the hip system manufacturer whereas the predicate Brainlab system has customized tools for implanting the different hip systems.

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.