



November 16, 2023

Blue Ortho
Matthieu Coic
QA RA Director
22 Chemin du Vieux Chene
Meylan, 38240
France

Re: K232521

Trade/Device Name: ExactechGPS® Total Ankle Application
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, LLZ
Dated: August 18, 2023
Received: August 18, 2023

Dear Matthieu Coic:

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,


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)
K232521

Device Name
ExactechGPS® Total Ankle Application

Indications for Use (Describe)

The ExactechGPS is intended for use during preoperative planning and during orthopedic surgery to aid the surgeon in locating anatomical structures and aligning the endoprosthesis with the anatomical structures provided that the required anatomical landmarks can be identified on the patient's preoperative CT scan.

The ExactechGPS Total Ankle Case Manager Application is specifically indicated for creating Total Ankle Navigation cases, uploading CT scans for reconstruction, download the reconstruction and export the reconstructed case to the Total Ankle Navigation Application.

The ExactechGPS Total Ankle Navigation Application is specifically indicated for Total Ankle Arthroplasty using the Vantage ankle system to aid the surgeon in locating anatomical structures and aligning the tibial and talar components with the anatomical structures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**ExactechGPS® Total Ankle Application
510(k) Summary of Safety and Effectiveness****I. SUBMISSION DATE**

August 18, 2023

II. SUBMITTER

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France
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III. US LOCAL AGENT

Exactech, Inc.
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Phone: 352-377-1140

IV. INFORMATION ON DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED**Primary Predicate**

<i>510(k) Number</i>	<i>Trade or Proprietary Model Name</i>	<i>Manufacturer</i>
#K213546	ExactechGPS Total Shoulder Application	Blue Ortho

This predicate has not been subject to a design-related recall.

V. PROPOSED DEVICE DESCRIPTION**Trade or Proprietary or Model Name(s):** ExactechGPS® Total Ankle Application**Common Name:** Surgical navigation system**Classification Name:** Orthopedic Stereotaxic Instrument (21 CFR 882.4560, product code OLO); Medical Image Communications Device (21 CFR 892.2020, product code LMD)**Classification:** Class II**Device Description:**The *ExactechGPS Total Ankle Application* proposed by Blue Ortho in this submission is new clinical software application.

The ExactechGPS Total Ankle Application (TAA) system is intended to be used during stereotaxic surgical procedures to aid the surgeons in locating anatomical structures and aligning the endoprosthesis with the patient bony anatomy provided that the required anatomical landmarks can be identified on the patient's preoperative CT scan.

The *ExactechGPS Total Ankle Application* is an Image Guided Surgery, or Navigation, system designed to guide surgeons during the preparation of the tibia and talar bones as part of a total ankle arthroplasty procedure. The *ExactechGPS Total Ankle Application* requires patient CT-scan data to undergo segmentation prior to being imported into the software, as part of reconstructing the bone model.

It encompasses two software applications:

- The *ExactechGPS Total Ankle Case Manager Application* is specifically indicated for creating Total Ankle Navigation cases, uploading CT scans for reconstruction, download the reconstruction and export the reconstructed case to the Total Ankle Navigation Application.
- The *ExactechGPS Total Ankle Navigation Application* is specifically indicated for Total Ankle Arthroplasty using the Vantage ankle system to aid the surgeon in locating anatomical structures and aligning the tibial and talar components with the anatomical structures.

The *ExactechGPS Total Ankle Navigation Application* is working on the Blue Ortho ExactechGPS System cleared per 510(k) #K213877. The system is composed of ExactechGPS Trackers, which are rigidly fixed to the patient bony anatomy, and other components (ExactechGPS Station and ExactechGPS camera) that are not in contact with the patient.

In the predicate device, a planning application is provided and indicated for pre-operative planning of surgical procedure. This submission does not propose planning pre-operative planning application. The others main principles of operation and technological principles between the predicate and the proposed device are similar.

VI. INDICATIONS FOR USE

The ExactechGPS is intended for use during preoperative planning and during orthopedic surgery to aid the surgeon in locating anatomical structures and aligning the endoprosthesis with the anatomical structures provided that the required anatomical landmarks can be identified on the patient's preoperative CT scan.

The *ExactechGPS Total Ankle Case Manager Application* is specifically indicated for creating Total Ankle Navigation cases, uploading CT scans for reconstruction, download the reconstruction and export the reconstructed case to the Total Ankle Navigation Application.

The *ExactechGPS Total Ankle Navigation Application* is specifically indicated for Total Ankle Arthroplasty using the Vantage ankle system to aid the surgeon in locating

anatomical structures and aligning the tibial and talar components with the anatomical structures.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

This proposed submission proposes the following differences compare to the ExactechGPS Total Shoulder Application predicate device:

- Different Indications for Use, as the patient joint treated during the surgical procedure in the proposed device is the ankle, and is the shoulder in the predicate device.
- In the predicate device, a planning application is provided and indicated for pre-operative planning of surgical procedure. This submission does not propose planning pre-operative planning application, but only a software application to manage surgical cases created by the user.
- Integration in the *ExactechGPS Total Ankle Navigation Application* of the Exactech total ankle systems, including Vantage Fixed Bearing or Mobile Bearing, Vantage 3D and Vantage 3D+, cleared in the following 510(k) submissions:

K152217	Vantage Total Ankle System
K183343	Vantage Total Ankle Flat Cut Talar Components
K230717	Vantage 3D/3D+

At a high level, the subject and predicate devices are based on the following same technological elements:

- The proposed device do not affect general device features and dimensions.
- The proposed device do not change the device computer language or other basic fundamental technologies.
- No changes to the hardware platform and localization system are proposed by this submission.

VIII. PERFORMANCE DATA

Testing information demonstrating safety and effectiveness of the *ExactechGPS Total Ankle Application* is supported by testing that was conducted in-house.

This submission includes or references the following non-clinical testing:

- Software verification testing to ensure all design outputs meet all specified requirements
- Software validation to ensure software specifications conform to user needs and intended uses

IX. SUBSTANTIAL EQUIVALENCE CONCLUSION

A comparison of specific features included in this submission demonstrates the proposed *ExactechGPS Total Ankle Application* is substantially equivalent to the cited predicate cleared per # K213546. The devices share identical intended use, identical general design features and basic fundamental scientific technology.