January 6, 2022

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

Re: K213546
Trade/Device Name: ExactechGPS Total Shoulder Application, Equinoxe Planning Software
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, LLZ
Dated: October 29, 2021
Received: November 8, 2021

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 (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/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 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 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, 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)*
K213546

Device Name
ExactechGPS® Total Shoulder 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 Shoulder Planning Application is specifically indicated for pre-operative planning of Total Shoulder Arthroplasty using the Equinoxe system. The ExactechGPS Total Shoulder Planning Application permits to visualize, measure and reconstruct anatomical structures in order to select and place the glenoid and humeral components.

The ExactechGPS Total Shoulder Navigation Application is specifically indicated for Total Shoulder Arthroplasty using the Equinoxe system to aid the surgeon in locating anatomical structures and aligning the glenoid component 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 Shoulder Application
510(k) Summary of Safety and Effectiveness

I. SUBMISSION DATE

October 29, 2021

II. SUBMITTER

BLUE ORTHO
22 Chemin du Vieux Chêne
38240 Meylan
France
Phone: +33 (0)4 58 00 35 25
Contact person: Matthieu COIC - Mail: matthieu.coic@blue-ortho.com

III. US LOCAL AGENT

Exactech, Inc.
2320 NW 66th Ct.
Gainesville, FL. 32653
Phone: 352-377-1140

IV. INFORMATION ON DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED

Primary Predicate

510(k) Number	*Trade or Proprietary Model Name*	*Manufacturer*
#K173372	ExactechGPS® Total Shoulder Application	Blue Ortho

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

Additional Predicates

510(k) Number	*Trade or Proprietary Model Name*	*Manufacturer*
#K203315	BLUEPRINT™ Patient Specific Instrumentation	TORNIER SAS

V. PROPOSED DEVICE DESCRIPTION

Trade or Proprietary or Model Name(s): ExactechGPS® Total Shoulder Application
Common Name: Surgical navigation system
Classification Name: Orthopedic Stereotaxic Instrument (21 CFR 882.4560, product code OLO); Picture Archiving & Communications System (21CFR 892.2050, product code LLZ)

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Classification: Class II

Device Description:

The *ExactechGPS Total Shoulder Application* proposed in this submission is a modification of the *ExactechGPS Total Shoulder Application* cleared per 510(k) #K173372.

The *ExactechGPS Total Shoulder Application* is an Image Guided Surgery, or Navigation, system designed to guide surgeons during the preparation of the glenoid as part of a total shoulder arthroplasty procedure. The *ExactechGPS Total Shoulder Application* also offers a preoperative planning feature that enables surgeons to plan a surgical intervention by evaluating implant size, type, and positioning using reconstructed patient bone models in a virtual environment. The *ExactechGPS Total Shoulder Application* requires patient CT-scan data to undergo segmentation prior to being imported into the software, as part of reconstructing the bone model, for both navigation and planning.

In the predicate device, the planning step was only indicated for pre-operative planning of the glenoid part of the Equinoxe system. This submission proposes the addition of the humeral component. Therefore, the proposed *ExactechGPS Total Shoulder Planning Application* permits to visualize, measure and reconstruct anatomical structures in order to select and place the glenoid and humeral components.

The proposed *ExactechGPS Total Shoulder Planning and Navigation Applications* integrate some other modifications compared to the predicate device. These modifications are documented in Letter to Files.

The proposed modifications do not change the ExactechGPS System general intended use, general design features, or basic fundamental scientific technology. No changes to the hardware platform or system accessories are proposed by this submission.

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 Shoulder Planning Application* is specifically indicated for pre-operative planning of Total Shoulder Arthroplasty using the Equinoxe system. The *ExactechGPS Total Shoulder Planning Application* permits to visualize, measure and reconstruct anatomical structures in order to select and place the glenoid and humeral components.

The *ExactechGPS Total Shoulder Navigation Application* is specifically indicated for Total Shoulder Arthroplasty using the Equinoxe system to aid the surgeon in locating anatomical structures and aligning the glenoid component with the anatomical structures.

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VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

This submission proposes the following modifications to the ExactechGPS Total Shoulder Application:

- Modification of the Indications for Use by proposing an extension of the pre-operative feature to the humeral component, and not only the glenoid component. This requires the modification of the *ExactechGPS Total Shoulder Planning Application* to extend the planning feature to the humeral part and components
- Extension of segmentation capabilities of Blue Ortho to the reconstruction of the humeral humerus
- Integration in the *ExactechGPS Total Shoulder Planning Application* of Exactech Equinoxe humeral implants cleared in the following 510(k) submissions:

K042021	Equinoxe Shoulder System
K063569	Equinoxe Reverse Shoulder System
K061454	Exactech Equinoxe Shoulder Stems
K082702	Exactech Equinoxe Reverse Shoulder System+15mm Humeral Adapter Tray
K093275	Exactech Equinoxe Reverse Shoulder System 36mm Glenosphere And Humeral Liner
K162726	Exactech® Equinoxe® Preserve Stem
K180632	Exactech Equinoxe Small Reverse Shoulder System

- Modification of the implementation of the registration algorithm by changing its initialization. This technical change in the registration algorithm has no impact on the global accuracy of the software nor performance.

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

- The modifications do not affect device intended use.
- The modifications do not affect general device features and dimensions.
- The modifications do not change the device computer language or other basic fundamental technologies.
- The modifications do not affect device accuracy and / or performance.
- No changes to the hardware platform or system accessories are proposed by this submission.

VIII. PERFORMANCE DATA

Testing information demonstrating safety and effectiveness of the *ExactechGPS Total Shoulder 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

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IX. SUBSTANTIAL EQUIVALENCE CONCLUSION

A comparison of specific features included in this submission demonstrates the proposed *ExactechGPS Total Shoulder Application* is substantially equivalent to the cited predicate cleared per #K173372. The devices share identical intended use, identical general design features and basic fundamental scientific technology.