January 26, 2024

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

Re: K233299
Trade/Device Name: ExactechGPS® System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instruments
Regulatory Class: Class II
Product Code: OLO
Dated: December 29, 2023
Received: December 29, 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

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)*
K233299

Device Name
ExactechGPS® System

Indications for Use *(Describe)*
The ExactechGPS® System is intended for use during stereotaxic surgery to aid the surgeon in locating anatomical structures and aligning the endoprostheses with the anatomical structures.

TKA Pro software application is specifically indicated for Total Knee Arthroplasty.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

22 Chemin du Vieux Chêne
38240 Meylan
France

ExactechGPS® System
510(k) Summary of Safety and Effectiveness

I. SUBMISSION DATE

September 29, 2023.

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

510(k) Number	*Trade or Proprietary Model Name*	*Manufacturer*
#K213877	ExactechGPS System	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® System
Common Name: Surgical navigation system
Classification Name: Orthopedic Stereotaxic Instrument (21 CFR 882.4560, product code OLO)
Classification: Class II
Device Description:
The ExactechGPS System proposed in this submission is a modification of the ExactechGPS System cleared per 510(k) #K213877.

The ExactechGPS System is an image-guided surgery, or navigation, system intended to be used during orthopedic surgical procedures to intraoperatively assist surgeons during arthroplasty. The ExactechGPS System enables surgeons to acquire intraoperative data by computing and displaying information such as distances, angles, and placement of prosthetic components in order to identify and characterize bone cuts necessary to achieve surgical goals.

The ExactechGPS System works with ExactechGPS hardware trackers that communicate intraoperative data to the ExactechGPS hardware station to provide surgeons with real-time information on the positions of patient anatomical structures and instrumentation used to prepare bone during stereotaxic surgery.

The proposed modifications do not change the ExactechGPS System general intended use, general design features, or basic fundamental scientific technology.

VI. INDICATIONS FOR USE

The Exactech GPS is intended for use during stereotaxic surgery to aid the surgeon in locating anatomical structures and aligning the endoprostheses with the anatomical structures.

TKA Pro software application is specifically indicated for Total Knee Arthroplasty.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

This submission proposes the following hardware modifications to the ExactechGPS system:

- A new optical localizer (or camera), to avoid obsolescence of sub-component and implement minor design improvements.
- A new Tablet component, to avoid obsolescence of previous Tablet. This new Tablet also implies minor design changes to the mechanical frame and other subcomponents of the station.
- The wireless feature is now provided by the Tablet itself, not anymore using a Wi-Fi dongle

The *ExactechGPS system* cleared per 510(k) #K213877 is compatible with the *ExactechGPS TKA Pro* clinical software applications.
The proposed *ExactechGPS system* that includes changes listed hereabove is compatible with the same *ExactechGPS TKA Pro* clinical software application.

Based on test bench testing, the proposed changes do not alter significantly the performances of the devices and the way it is used:

- The proposed *ExactechGPS system* have the same general features and dimensions, with the same technology and performances.

- The redesigned electronic card only resolves obsolescence issues with no impact on user, global performances and safety.
- The use of the native Wi-Fi feature of the tablet only allow to retrieve the external additional dongle used with the predicate device.

VIII. PERFORMANCE DATA

Testing information demonstrating safety and effectiveness of the *ExactechGPS System* in the intended environment of use is supported by testing that was conducted in-house and by accredited testing laboratories.
This submission includes or references the following non-clinical testing:

- General Functions tests to ensure design is fully verified and validated.
- Electrical safety testing per IEC 60601-1 demonstrated the proposed *ExactechGPS System* is compliant with the requirements of the standard.
- EMC Compatibility testing per IEC 60601-1-2 demonstrated the proposed *ExactechGPS System* is compliant with the requirements of the standard.
- Analysis of photobiological safety per EN 62471 demonstrated the proposed *ExactechGPS System* is compliant with the requirements of the standard.
- Sterilization validation per ISO 11135-1:2014 demonstrated the proposed ExactechGPS Sterile Drape is compliant with the requirements of the standard.

IX. SUBSTANTIAL EQUIVALENCE CONCLUSION

A comparison of specific features included in this submission demonstrates the proposed ExactechGPS System is substantially equivalent to the cited predicate cleared per #K213877. The devices share identical intended use, identical general design features and basic fundamental scientific technology.