



September 2, 2020

Blue Ortho
Matthieu Coic
QA RA Director
6 Allee de Bethleem
38610 Gieres, France

Re: K193618
Trade/Device Name: ExactechGPS System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 3, 2020
Received: June 5, 2020

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, MPH
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)
K193618

Device Name
ExactechGPS System

Indications for Use (Describe)

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

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ExactechGPS® System 510(k) Summary

I. SUBMISSION DATE:

June 03, 2020

II. SUBMITTER:

BLUE ORTHO

6 Allée de Bethléem

38610 Gières

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:

<i>510(k) Number</i>	<i>Trade or Proprietary Model Name</i>	<i>Manufacturer</i>
#K152764	EXACTECH GPS	Blue Ortho

V. PROPOSED DEVICE DESCRIPTION

Trade or Proprietary or Model Name(s): ExactechGPS® System – TKA Pro software application

Common Name: Orthopedic Stereotaxic system

Classification Name: 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) #K152764.

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 camera

component that communicates with trackers is compliant with EN 62471 (Photobiological safety testing).

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 endoprotheses 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 to improve lifetime of the product.
- The addition of wireless capabilities for pre-operative and post-operative transfer of information such as log files or surgical plan files between the ExactechGPS System a remote device (mobile phone, tablet...).
- Update the operating system from Windows 7-64 to Windows 10-64

The *ExactechGPS system* cleared per 510(k) #K152764 is compatible with the entire Knee Clinical Applications Software suite (which includes *ExactechGPS TKA Pro*, *ExactechGPS TKA Plus* and *ExactechGPS RTKA*).

The proposed *ExactechGPS system* that includes changes listed hereabove is compatible only with the *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 optical localizer (or camera) proposes the same general features and dimensions, with the same technology and accuracy and safety performances
- The proposed wireless technology is not used intraoperatively, therefore has no impact on the therapeutic objectives and performances
- The proposed Windows 10 operating system has no impact on the user and aims to comply with the current state of the art for products running on this operating system.

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 determined the proposed ExactechGPS System is compliant with the requirements of the standard.
- EMC Compatibility testing per IEC 60601-1-2 determined the proposed ExactechGPS System 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 #K152764. The devices share identical intended use, identical general design features and basic fundamental scientific technology.