November 24, 2017

Blue Ortho
Anthony Boyer
President and CEO
6 Allee de Bethleem
Gieres, 38610
France

Re: K173372
Trade/Device Name: ExactechGPS Total Shoulder Application
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, LLZ
Dated: October 26, 2017
Received: October 27, 2017

Dear Anthony Boyer:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173372

Device Name
ExactechGPS® Total Shoulder Application

Indications for Use *(Describe)*

The ExactechGPS is intended for use during preoperative planning and during stereotaxic 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 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
SPECIAL 510(k) – 510(k) Summary of Safety and Effectiveness

Submission date:
October 26, 2017

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Gainesville, FL. 32653
Phone: 352-377-1140

Trade or Proprietary or Model Name(s):
ExactechGPS® Total Shoulder Application

Common Name:
Surgical navigation system and preoperative planning tool

Classification Number
21 CFR 882.4560

Classification Name:
Orthopedic Stereotaxic Instrument, Picture Archiving & Communications System

Classification
Class II

Product Code
OLO (21 CFR 882.4560), LLZ (21CFR 892.2050)

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Information on Devices to which Substantial Equivalence is Claimed:
Primary Predicate

510(k) Number	*Trade or Proprietary Model Name*	*Manufacturer*
#K162567	ExactechGPS® Total Shoulder Application	Blue Ortho

Indications for Use:
The ExactechGPS is intended for use during preoperative planning and during stereotaxic 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 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.

Device Description:
This submission proposes modifications to the ExactechGPS Total Shoulder Application cleared per #K162567.

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.

At initial release, the segmentation step was manually conducted by Blue Ortho. This submission proposes the addition of a semi-automatic segmentation option, where surgeons can elect to not send the CT exams to Blue Ortho for segmentation but employ a semi-automatic segmentation process to virtually reconstruct the bony anatomy of the patient in three dimensions. The use of semi-automatic segmentation to virtually recreate patient bone is available for planning only, and not for use during a navigated surgical procedure.

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

- Software verification testing to ensure all design outputs meet all specified requirements
- System accuracy verification via comparison of system outputs to CT-scan data collected during clinical use
- Software validation to ensure software specifications conform to user needs and intended uses

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Testing demonstrates the modified ExactechGPS Total Shoulder Application is substantially equivalent to the cited predicate.

Summary of Technological Characteristics

The rationale for substantial equivalence is based on consideration of the following characteristics:

- Intended use: the modifications do not affect device intended use.
- General design features and dimensions: the modifications do not affect general device features and dimensions.
- Basic fundamental scientific technology: the modifications do not change the device computer language or other basic fundamental technologies.
- Performance specifications: the modifications do not affect device accuracy and / or performance.
- Hardware platform: no changes to the hardware platform or system accessories are proposed by this submission.

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. The devices share:

- Identical Indications for Use statements
- Identical intended use
- Identical technology for stereotaxic surgery
- Similar, equivalent technology for preoperative planning

The information provided by Blue Ortho in this application confirms the proposed ExactechGPS Total Shoulder Application is substantially equivalent to the predicate cleared per #K162567.