DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 5, 2017

Blue Ortho
Anthony Boyer
President
5 Avenue Du Grand Sablon
La Tronche, 38700 FR

Re: K162567
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: March 6, 2017
Received: March 10, 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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)*
K162567

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.

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."

6 Allée de Bethléem
38610 Gières
France

ExactechGPS® Total Shoulder Application
510(k) Summary of Safety and Effectiveness

Submission date:
September 08, 2016

Sponsor:
BLUE ORTHO
6 Allée de Bethléem
38610 Gières France
Phone: +33 (0) 4 58 00 35 25

Contact:
Anthony BOYER
Phone: +33 (0) 4 76 54 95 46
Cell: +33 (0)6 30 39 50 66
anthony.boyer@blue-ortho.com

US Local Agent
Exactech, Inc.
2320 NW 66th Ct.
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)

6 Allée de Bethléem
38610 Gières
France

Information on Devices to which Substantial Equivalence is Claimed:

Primary Predicate

510(k) Number	*Trade or Proprietary Model Name*	*Manufacturer*
#K152764	EXACTECH GPS	Blue Ortho

Additional Predicates

510(k) Number	*Trade or Proprietary Model Name*	*Manufacturer*
#K063408	CTLOGICS Navigation System	Praxim
#K151568	OrthoVis Preoperative Plan	Arthrex

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:

The ExactechGPS Total Shoulder Application is a modification of the Exactech GPS stereotactic navigation system designed to help guide surgeons during the preparation of the glenoid as part of a total shoulder arthroplasty procedure.

Like predicate Exactech GPS system software dedicated to use with total knee arthroplasty procedures, the ExactechGPS Total Shoulder Application works with Exactech GPS hardware trackers that communicate intraoperative data to the Exactech GPS hardware station to provide surgeons with real-time information on the position of patient anatomical structures and of instrumentation used to prepare patient bone during stereotaxic surgery.

The ExactechGPS Total Shoulder Application adds a preoperative planning feature, where surgeons use CT-scan images of patient bone with software models of Exactech Equinoxe implants to preoperatively plan procedures in a virtual environment prior to surgery.

The ExactechGPS Total Shoulder Application is used with the same ExactechGPS V2 station, trackers, and disposable kit hardware as the predicate ExactechGPS. This submission includes new surgical instruments dedicated to total shoulder arthroplasty.

The ExactechGPS Total Shoulder Application with Exactech Equinoxe implants cleared in the following 510(k) submissions:

K042021	Equinoxe Shoulder System

K063569	Equinoxe Reverse Shoulder System
K093275	Equinoxe Reverse Shoulder System 36mm Glenosphere and Humeral Liners
K093430	Equinoxe XL Keeled, XL Pegged, and Cage Glenoid
K103419	Equinoxe UHMWPE Posterior Augment Pegged Glenoids
K110708	Equinoxe Reverse Shoulder Line Extensions
K113309	Equinoxe Cage Glenoids
K121220	Equinoxe UHMWPE 16° Posterior Augment Pegged Glenoids
K131575	Equinoxe Reverse Shoulder System Superior Posterior Augmented Glenoid Baseplates

Substantial Equivalence Conclusion:
A comparison of key features and attributes included in this submission demonstrates the proposed ExactechGPS Total Shoulder Application is substantially equivalent to the cited predicate devices. The devices share:

- Equivalent indications for use statements
- Equivalent intended use
- Equivalent technology

Testing:
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, and that the particular requirements implemented through software can be consistently fulfilled
- System accuracy verification via bench testing to ensure the ExactechGPS Total Shoulder Application works with Exactech GPS hardware to display information to surgeons as intended
- System accuracy verification via comparison of system outputs to CT-scan data collected during simulated use via evaluation with cadaveric specimens
- Overall system validation through simulated use via evaluation with cadaveric specimens