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

July 13, 2016

BLUE ORTHO
Mr. Anthony Boyer
President
5 avenue du Grand Sablon
La Tronche, 38700
FRANCE

Re: K152764
Trade/Device Name: EXACTECH GPS
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: HAW
Dated: June 9, 2016
Received: June 13, 2016

Dear Mr. 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 Parts 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" (21CFR 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 yours,

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)*
K152764

Device Name

EXACTECH GPS

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 endoprostheses with the anatomical structures.

It is specifically indicated for primary and revision 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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38700 La Tronche
France

BLUE NAVIGATION SYSTEM
TRADITIONAL 510(k) – 510(k) Summary of Safety and Effectiveness

Submission date:	June 09, 2016
Sponsor	BLUE ORTHO 5 avenue du Grand Sablon 38700 La Tronche France Phone: +33 (0) 4 76 54 95 46
Contact	Anthony BOYER Phone: +33 (0) 4 76 54 95 46 Cell: +33 (0)6 30 39 50 66 anthony.boyer@blue-ortho.com
U.S. Headquarters	Exactech, Inc. 2320 NW 66th Ct. Gainesville, FL. 32653 Phone: 352-377-1140
Trade Name	EXACTECH GPS
Common Name	Stereotaxic Instruments
Classification Name	Stereotaxic Instrument (21 CFR 882.4560, Product Code OLO Class II)
Information on devices to which substantial equivalence is claimed:	510(k) Number: K100742 Trade or Property Model Name: Exactech GPS Manufacturer: BLUE ORTHO
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. It is specifically indicated for primary and revision Total Knee Arthroplasty.

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Device Description:

The EXACTECH GPS is an Image Guided Surgery, or Navigation, system for orthopedic surgical procedures intended to be used to intraoperatively assist surgeons during total knee arthroplasty. The EXACTECH GPS 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 predicate device is the EXACTECH GPS cleared in K100742. Both predicate and proposed device have the same intended use, general design features, and basic fundamental scientific technology.

Compare to the predicate device cleared in K100742, this submission proposes changes to:

- Sterile battery sterilization packaging
- Introduction of the *Revision Total Knee Application* software

Testing

Sterile battery:

- Process qualifications related to packaging and sterilization
- Shelf life validation

Revision Total Knee Application software:

- Design Verification (including accuracy testing)
- Design Validation (including cadaveric sessions)

Summary of Technological Characteristics

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

- **Intended Use:** the proposed modifications do not affect device intended use.
- **General Design Features and Dimensions:** the proposed modifications do not affect key device features and dimensions.
- **Shelf life of the sterile components:** proposed and predicate devices have the same shelf life.
- **Basic fundamental scientific technology:** the proposed modifications do not change the device computer language and / or localization technology.
- **Performance Specifications:** the proposed modifications do not affect device accuracy and / or performance.

Substantial Equivalence Conclusion

Proposed device was tested during engineering studies and testing ensures Results of engineering studies and cadaveric sessions referenced in this 510(k) submission demonstrate the proposed EXACTECH GPS is substantially equivalent to the predicate.