NOV 21 2011

Exactech® Gibralt™ Spine System Facet Screw
Traditional 510(k)

510(k) Summary

Company:	Exactech®, Inc 2320 NW 66th Court Gainesville, FL 32653
Date:	October 5, 2011
Contact Person:	Vladislava Zaitseva Regulatory Affairs Specialist Phone: (352) 377-1140 Fax: (352) 378-2617
Proprietary Name:	Exactech® Gibralt™ Spine System Facet Screw
Common Name:	Facet screw spinal device
Classification Name:	Unclassified
Product Code:	MRW

Legally Marketed Devices to Which Substantial Equivalence Is Claimed

- TranS1 Facet Screw (K073515)
- Spartan S3 Facet System (K092568)
- Corridor Fixation System (K083442)
- US Spine Facet Fixation System (K061041)
- DePuy AcroMed Discovery Facet Screw (K012773)
- SpineFrontier Chameleon Fixation System (K071420)

Device Description

The proposed Gibralt Spine System Facet Screw is a new facet screw device intended to provide posterior fixation as an aid to fusion. The Gibralt Spine System Facet Screw components are available in a variety of sizes and are manufactured from titanium alloy per ASTM F136.

The system components are provided non-sterile. The products must be steam sterilized by the hospital prior to use.

The Gibralt Spine System Facet Screw is provided with a complete instrumentation system to assist the surgeon in implantation according to a traditional open surgical procedure.

Indications for Use

The Gibralt Spine System Facet Screw is indicated for posterior surgical treatment at C2-S1 (inclusive) spinal levels for the following: DDD (neck pain of discogenic origin with

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- A biomechanical assessment comparing Gibralt Facet Screw mechanical performance to cited predicate devices.

The results of mechanical testing and analysis demonstrate the proposed device is substantially equivalent to cited predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

NOV 21 2011

Exactech, Inc.
% Ms. Vladislava Zaitseva
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K112097
Trade/Device Name: Gibralt Spine Systems Facet Screw
Regulatory Class: Unclassified
Product Code: MRW
Dated: October 05, 2011
Received: October 12, 2011

Dear Ms. Zaitseva:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Erin M Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Gibralt™ Spine System Facet Screw
Traditional 510(k)

Indications for Use Statement

510(k) Number: K112097

Device Name: Exactech® Gibralt™ Spine System Facet Screw

INDICATIONS FOR USE:
The Gibralt Spine System Facet Screw is indicated for the posterior surgical treatment at C2- S1 (inclusive) spinal levels for the following: DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spondylolysis, fracture, or failed previous fusion.

Prescription Use X **and/or** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

Please do not write below this line – use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112097