



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

Exactech, Incorporated  
% Mr. Kenneth C. Maxwell II  
Regulatory and Quality Specialist  
Empirical Testing Corporation  
4628 Northpark Drive  
Colorado Springs, Colorado 80918

June 28, 2016

Re: K160697

Trade/Device Name: Gibralt® Spine System and Gibralt® Occipital Spine System  
Regulatory Class: Unclassified  
Product Code: NKG, KWP  
Dated: May 31, 2016  
Received: June 1, 2016

Dear Mr. Kenneth C. Maxwell II:

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

**Indications for Use**

510(k) Number (if known)  
K160697

Device Name  
Gibralt® Spine System

Indications for Use (Describe)

The Gibralt® Spine System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1-C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Gibralt® Spine System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Gibralt® Spine System may be connected to the Gibralt® Occipital Spine System with rod-to-rod connectors. The Gibralt® Spine System may also be connected to the Exactech® Proliant® System, Exactech® Silverbolt® and Mainframe® Spinal Screw Systems, or Exactech® Hydralok® Exactech, using rod-to-rod connectors and transitional rods. Refer to the specific system package inserts for a list of their indications for use.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

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*PRASStaff@fda.hhs.gov*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration <b>Indications for Use</b>	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement on last page.
510(k) Number <i>(if known)</i> K160697	
Device Name <b>Gibralt® Occipital Spine System</b>	
Indications for Use <i>(Describe)</i>  <p>When used with the Gibralt® Spine System, the Gibralt® Occipital Spine System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7), and the thoracic spine from T1 - T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Gibralt® Occipital Spine System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.</p> <p>In order to achieve additional levels of fixation, the Gibralt® Occipital Spine System may be connected to the Gibralt® Spine System, using rod-to-rod connectors. Refer to the Gibralt® Spine System package insert for a list of the Gibralt® Spine System indications of use.</p> <p>The Occipital Bone Screws are limited to occipital fixation only.</p>	
Type of Use (Select one or both, as applicable) <input checked="" type="checkbox"/> Prescription Use (Part 21 CFR 801 Subpart D) <input type="checkbox"/> Over-The-Counter Use (21 CFR 801 Subpart C)	
<b>PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.</b>	
<b>FOR FDA USE ONLY</b>	
Concurrence of Center for Devices and Radiological Health (CDRH) <i>(Signature)</i>          	

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## 5. 510(K) SUMMARY

Submitter's Name:	Exactech, Inc.
Submitter's Address:	2320 NW 66th Court Gainesville, FL 32658
Submitter's Telephone:	352.377.1140
Contact Person:	Kenneth C. Maxwell II Empirical Testing Corp. 719.291.6874
Date Summary was Prepared:	23 June 2016
Trade or Proprietary Name:	Gibralt® Spine System Gibralt® Occipital Spine System
Common or Usual Name:	Orthosis, Cervical Spinal Pedicle Fixation Appliance, Fixation, Spinal Interlaminar
Classification:	Unclassified , Class II per 21 CFR §888.3050
Product Code:	NKG, KWP
Classification Panel:	Orthopedic Devices

### DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The line extension and device modifications for the Gibralt® Spine System are intended to provide immobilization and stabilization of spinal segments in the upper thoracic, cervical, and occipital spine. The system components are manufactured from titanium and cobalt chromium. The modifications included in the scope of this submission are: expanded indications for use for both systems, incorporation of design changes, and addition of new components.

### INDICATIONS FOR USE

#### Gibralt® Spine System:

The Gibralt® Spine System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1-C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Gibralt® Spine System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Gibralt® Spine System may be connected to the Gibralt® Occipital Spine System with rod-to-rod connectors. The Gibralt®

Spine System may also be connected to the Exactech® Proliant® System, Exactech® Silverbolt® and Mainframe® Spinal Screw Systems, or Exactech® Hydralok® Exactech, using rod-to-rod connectors and transitional rods. Refer to the specific system package inserts for a list of their indications for use.

#### Gibralt® Occipital Spine System:

When used with the Gibralt® Spine System, the Gibralt® Occipital Spine System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7), and the thoracic spine from T1 - T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Gibralt® Occipital Spine System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Gibralt® Occipital Spine System may be connected to the Gibralt® Spine System, using rod-to-rod connectors. Refer to the Gibralt® Spine System package insert for a list of the Gibralt® Spine System indications of use.

The Occipital Bone Screws are limited to occipital fixation only.

The indications for use for the Gibralt® Spine System and the Gibralt® Occipital Spine System are similar to that of the predicate devices in Table 5-1.

#### TECHNOLOGICAL CHARACTERISTICS

Gibralt® Spine System components are made from materials that conform to titanium per ASTM F136 and cobalt chromium per ASTM F1537. The Gibralt® Occipital Spine System components are made from materials that conform to titanium per ASTM F136. The subject and predicate devices have similar technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are similar between the subject and predicates:

- Indications for Use
- Materials of Manufacture

Table 5-1 Predicate Devices

<b>510k Number</b>	<b>Trade or Proprietary or Model Name</b>	<b>Manufacturer</b>	<b>Type</b>
K142838	Synapse Occipital-Cervical-Thoracic System	Synthes USA	Primary Predicate
K083071	VERTEX™ Reconstruction System	Medtronic	Reference
K050979	S4 Spinal System	Aesculap®, Inc.	Reference

#### PERFORMANCE DATA

The proposed line extensions and modified Gibralt® Spine System have been tested in the following test modes:

- Static axial compression per ASTM F1717-14
- Static axial compression bending per ASTM F1717-14
- Dynamic axial compression per ASTM F1717-14
- Dynamic axial compression bending per ASTM F1717-14

The results of this non-clinical testing show that the strength of the Gibralt® Spine System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

#### CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Gibralt® Spine System and Gibralt® Occipital Spine System are substantially equivalent to the predicate devices.