



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

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

May 11, 2015

Re: K150152

Trade/Device Name: Octane<sup>®</sup> Straight Intervertebral Fusion Device, Ti Coated  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: April 13, 2015  
Received: April 14, 2015

Dear Mr. Maxwell:

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" (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 <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> K150152	
Device Name Octane® Straight Intervertebral Fusion Device, Ti Coated	
Indications for Use <i>(Describe)</i> The Octane® Straight Intervertebral Fusion Device, Ti Coated is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with Degenerative Disc Disease (DDD,) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature, and have had at least 6 months of non-operative treatment. The device is intended for use with autogenous graft, and with supplemental fixation systems cleared for use in the lumbosacral spine.	
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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This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(K) SUMMARY

Submitter's Name:	Exactech, Inc.
Submitter's Address:	2320 NW 66th Court Gainesville, FL 332653
Submitter's Telephone:	352.377.1140
Contact Person:	Kenneth C. Maxwell Empirical Testing Corp. 719.291.6874
Date Summary was Prepared:	16-Jan-15
Trade or Proprietary Name:	Octane® Straight Intervertebral Fusion Device, Ti Coated
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	Orthopedic

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

The Exactech® Octane® Straight Spinal Implant is an implant constructed of medical grade Polyetheretherketone, (PEEK-OPTIMA® LT1). The implant incorporates ridges on the superior and inferior surfaces to resist expulsion. The device is open in the transverse plane to allow insertion of bone graft prior to placement, and fenestrated along the sides. The radiolucent PEEK-OPTIMA® material allows visualization of the defect site on radiography to assess bone growth, and incorporates tantalum markers to permit verification of position. The device is plasma coated with commercially pure titanium. The Octane Straight Spinal Implant is provided sterile for single use.

The purpose of this submission is the addition of a CP-Ti coating on a previously cleared lumbar intervertebral fusion device.

### INDICATIONS FOR USE

The Octane® Straight Intervertebral Fusion Device, Ti Coated is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with Degenerative Disc Disease (DDD,) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature, and have had at least 6 months of non-operative treatment. The device is intended for use with autogenous graft, and with supplemental fixation systems cleared for use in the lumbosacral spine.

The indications for use for the Octane® Straight Intervertebral Fusion Device, Ti Coated is similar to that of the predicate devices listed in Table 5-1.

## TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness.

Table 5-1 Predicate Devices

<b>510k Number</b>	<b>Trade or Proprietary or Model Name</b>	<b>Manufacturer</b>	<b>Type</b>
K130434	Octane® Straight Intervertebral Fusion Device	Exactech, Inc.	Primary
K112036	Calix™ PC Spinal Implant System	X-Spine	Reference

## PERFORMANCE DATA

The Octane® Straight Intervertebral Fusion Device, Ti Coated has been tested in the following test modes:

- Static axial compression per ASTM F2077
- Static compressive shear per ASTM F2077
- Dynamic axial compression per ASTM F2077
- Dynamic compressive shear per ASTM F2077
- Percent Porosity per ASTM F1854-09
- Coating Thickness per ASTM F1854-09
- Static Shear per ASTM F1044-05
- Static Tensile per ASTM F1147-05
- Shear Fatigue per ASTM F1160-05
- Abrasion per ASTM F1978-00

The results of this non-clinical testing show that the strength of the Octane® Straight Intervertebral Fusion Device, Ti Coated 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 Octane® Straight Intervertebral Fusion Device, Ti Coated is substantially equivalent to the predicate device.