Exactech® Octane® Straight Intervertebral Fusion Device
510(k) Summary

MAY 1 2013

Sponsor: Exactech® Inc.
2320 N.W. 66th Court
Gainesville, FL 32653

Phone: (352) 327-4762
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FDA Establishment Number 1038671

Contact: Patrick Hughes
Senior Regulatory Affairs Specialist

Date: May 1, 2013

Trade or Proprietary or Model Name(s):
Exactech® Octane® Straight Intervertebral Fusion Device

Common Name:
Intervertebral body fusion device

Classification Name:
21 CFR 888.3080 – Intervertebral body fusion device

Product Code:
MAX

FDA Classification:
Class II

Predicate Device:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K082270	Octane® P Intervertebral Body Fusion Device	Exactech

Exactech® Octane® Straight Intervertebral Fusion Device
510(k) Summary

Indications for Use:
The Octane Straight Intervertebral Fusion Device 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.

Device Description:

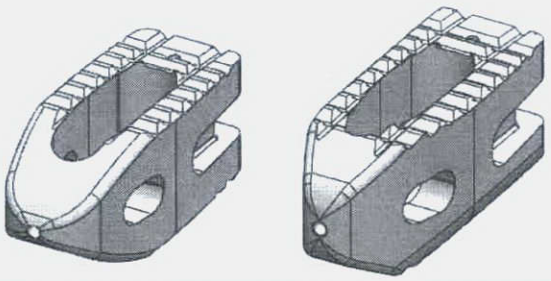

Figure 1: Octane Straight Intervertebral Fusion Device implant options

Proposed Octane Straight Intervertebral Fusion Device components (Figure 1) are line extensions of the Octane interbody fusion device system cleared for US distribution per 510(k) #K082270.

Comparison of Technological Characteristics
Both predicate and proposed devices have the same intended use, basic fundamental scientific technology, and share the following similarities:

- the same indications for use
- similar design features
- the same materials
- the same 8-year shelf life
- packaging and sterilization using the same materials and processes

The proposed Octane Straight components are not being submitted as the result of a recall or any corrective action related to the Octane product lines.

Non-Clinical Performance Data
Table 1 shows non-clinical performance data provided, cited, or referenced in this submission to support a conclusion of substantial equivalence:

Table 1: Octane Straight Non-Clinical Performance Data

Evaluation	Activities Performed
Loss of mechanical integrity: fracture/breakage	Static compression testing per ASTM F2077
	Dynamic compression testing per ASTM F2077
	Static compressive shear testing per ASTM F2077
Implant subsidence	Subsidence Yield Force per ASTM F2267

Substantial Equivalence Conclusion:
Comparison analysis and results of engineering studies referenced in this 510(k) submission demonstrate proposed Octane Straight Intervertebral Fusion Device implants are substantially equivalent to cited predicate devices cleared for US distribution.

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

May 1, 2013

Exactech®, Incorporated
% Mr. Patrick Hughes
Senior Regulatory Affairs Specialist
2320 Northwest 66th Court
Gainesville, Florida 32653

Re: K130434
Trade/Device Name: Exactech® Octane® Straight Intervertebral Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 18, 2013
Received: March 19, 2013

Dear Mr. Hughes:

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 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. 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 D. Keith

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

Enclosure

Exactech® Octane® Straight Intervertebral Fusion Device
Special 510(k) – Indications for Use

510(k) Number: K130434

Device Name: Exactech® Octane® Straight Intervertebral Fusion Device

INDICATIONS

The Octane Straight Intervertebral Fusion Device 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.

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)

Ronald P. Jean -S

(Division Sign-Off)

Division of Orthopedic Devices

510(k) Number: K130434