

K061385

APPENDIX III (510(k) Summary)

MAY 30 2007

Product: OSStaple™ Staple System

BioMedical Enterprises, Inc. (BME) intends to introduce additional indications for the OSStaple™ System consisting of shape memory Nitinol staples (the "OSStaple™" and "OSSplate™") and accessories for setting and warming the staples to achieve compression.

a. Submitter Information

BioMedical Enterprises, Inc.
14785 Omicron Drive, Ste. 205
San Antonio, Texas 78245
Telephone: (210) 677-0354
Contact: Dr. W. Casey Fox (CEO)

Date Prepared: August 8, 2006

- b. Classification name: Appliance, Fixation, Spinal Intervertebral Body
Common/Usual Name: Spinal Intervertebral body fixation orthosis
Proprietary Name: OSStaple™ Staple System
Product Code: KWQ
Regulation Number: 888.3060

c. Intended Use:

Additional indications for the OSStaple™ are:
For use in conjunction with traditional rigid fixation in cervical fusion procedures as a means to maintain the relative position of bony tissue such as allografts or autografts. This device is for use with traditional rigid fixation devices such as the Ransford Loop, Hartshill rectangles, cerclage wiring or other legally marketed cervical spine stabilization device. This device is not intended to be used alone for load bearing applications.

d. Device Description


The OSStaple™ Staple system consists of two prong staples fabricated from Nitinol. The staple's prongs are parallel during insertion. Application of an electrical current from the OSSforce™ Controller to the staple causes the staple prongs to deflect inward and the "S" shaped back to contract until constrained. This inward deflection and contraction causes staple retention. This device is for use with traditional rigid fixation devices such as the Ransford Loop, Hartshill rectangles, cerclage wiring or other legally marketed cervical spine stabilization device.

e. Substantial Equivalence:

The OSSStaple™ Staple System is substantially equivalent to the Medicea C-JAWS Cervical Compressive Mini Frame (K062181) and the Depuy BOWTI™ Anterior Buttress Staple (K021039)

The FDA has classified these equivalent devices as Class II devices (e.g. 21 CFR, 888.3060). The OSSStaple™ Staple System is a Class II medical device.

The OSSforce™ Controller heating unit was approved via 510(k) K023203 for orthopedic use, K023486 for maxillofacial use, K023488 for craniofacial use and no modifications are required for the additional indications. The OSSforce™ Controller uses the joule (heating) effect of electrical current in a conductor to increase the temperature of the Nitinol staple (as the conductor) allowing it to return to its stable austenitic phase position thereby causing compression. Circuitry controls the heating effect and prevents tissue damage by limiting current and time.



(Signature)

W. Casey Fox, Ph.D. P.E.
CEO
BioMedical Enterprises, Inc.

5/29/07

(Date)



MAY 30 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomedical Enterprises, Inc.
% W. Casey Fox, Ph.D., P.E.
President
14785 Omicron Drive, Suite 205
San Antonio, Texas 78245

Re: K061385
Trade Name: OSStaple™ System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: May 17, 2007
Received: May 21, 2007

Dear Dr. Fox:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

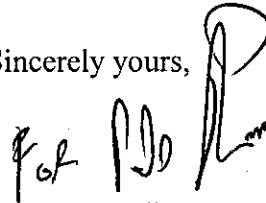
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

Page 2 – W. Casey Fox, Ph.D., P.E.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or at Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'M. Melkerson', is written over a large, stylized capital letter 'P'.

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

Enclosure

APPENDIX II (Indication for Use)

Device Name: OSSStaple™ Staple System

Additional indications for the OSSStaple™ are:

For use in conjunction with traditional rigid fixation in cervical fusion procedures as a means to maintain the relative position of bony tissue such as allografts or autografts. This device is for use with traditional rigid fixation devices such as the Ransford Loop, Hartshill rectangles, cerclage wiring or other legally marketed cervical spine stabilization device. This device is not intended to be used alone for load bearing applications.

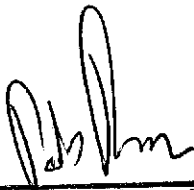
Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

(Optional Format 1-2-96)

510(k) Number 120613881