



Food and Drug Administration
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In2Bones SAS
% Dr. Norman Estrin, Ph.D.
Managing Partner
Estrin Consulting Group LLC
9109 Copenhaver Drive
Potomac, Maryland 20854

February 18, 2016

Re: K153395
Trade/Device Name: OS2[®] -C Compression Staple
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: November 22, 2015
Received: November 24, 2015

Dear Dr. Estrin:

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)
K153395

Device Name
OS2®-C Compression Staple

Indications for Use (Describe)

The OS2®-C Compression Staples are indicated for fixation of arthrodesis, osteotomies and fractures in hand or foot surgery.

The number and size of the OS2®-C Compression Staples must be adapted to the indication.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
For In2Bones OS2®-C Compression Staple

Sponsor identification	In2Bones SAS 28 chemin du Petit Bois 69130 Ecully – France Phone: +33.4.72.29.26.26 Fax: +33.4.72.29.26.29
Establishment registration number	3010470577
Date of preparation	November 20, 2015
Contact person	Norman F. Estrin, Ph.D. Estrin Consulting Group LLC 9109 Copenhaver Drive Potomac, MD 20854 Phone: (301) 279-2899 Email: estrin@yourFDAconsultant.com
Authorized Agent in the United States	Norman F. Estrin, Ph.D. Estrin Consulting Group LLC 9109 Copenhaver Drive Potomac, MD 20854 Phone: (301) 279-2899 Email: estrin@yourFDAconsultant.com
Proprietary Name	OS2®-C Compression Staple
Common name	Bone Compression staple
Device classification regulation	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories Class II
Device Product Code and Panel	JDR: staple, fixation, bone 87 orthopedics

Device Description	<p>The OS2®-C Compression Staple is an osteosynthesis staple, enabling a constant and reproducible compression.</p> <p>The OS2®-C Compression Staple is available in multiple lengths and interaxis. It is delivered sterile, ready to use, pre-assembled on its inserter.</p> <p>The implant is manufactured from PEEK-OPTIMA®, polymer from Invibio®, and is designed for single use only.</p> <p><u>Sizes:</u></p> <p>The OS2®-C Compression Staple is available in various interaxis from 11mm to 15mm.</p> <p><u>Material:</u></p> <p>The OS2®-C Compression Staple is manufactured from PEEK according to standard ASTM F2026.</p> <p>It does not have any coating.</p> <p><u>Single use:</u></p> <p>The OS2®-C Compression Staple is designed for single use only.</p> <p><u>Sterilization:</u></p> <p>The OS2®-C Compression Staple is supplied sterile, using gamma irradiation.</p> <p><u>Place of use:</u></p> <p>The OS2®-C Compression Staple is indicated for use in a hospital, or outpatient surgery center where sterile field may be created and maintained.</p>
Predicate Devices	<p>Biotech International / EOS Eleos Memory Staple (K112794)</p> <p>Integra / Newdeal UNI-CLIP (K011716)</p> <p>Memometal Easyclip (K070031)</p> <p>Smith and Nephew Bioraptor 2.3 PK suture anchor (K071586) - PEEK</p>
Indications for use:	<p>The OS2®-C Compression Staples are indicated for fixation of arthrodesis, osteotomies and fractures in hand or foot surgery.</p> <p>The number and size of the OS2®-C Compression Staples must be adapted to the indication.</p>
Comparison of the indications for use with the predicate devices:	<p>As with the predicate devices, the OS2®-C Compression Staple is indicated for surgical implantation longer than 30 days in the fixation of bone fractures or for bone reconstruction in hand and foot.</p>
Comparison of Technological characteristics	<p>The technological characteristics of the OS2®-C Compression Staple are the same as the characteristics of predicate devices in terms of intended use and design. All these implants have the following features:</p> <ul style="list-style-type: none"> - <u>Insertion into bone:</u> The OS2®-C Compression Staple and all predicate devices are intended for surgical implantation into bone for longer than 30 days. - <u>Design:</u> The OS2®-C Compression Staple has partially similar design, when compared to the Integra / Newdeal UNI-CLIP

(K011716), Memometal Easyclip (K070031), Biotech International / EOS Eleos Memory Staple (K112794) and Memometal Easyclip (K070031); all are compression staples with various interaxis and leg lengths in the range. Any differences of design from staple to staple do not affect the Safety and Effectiveness of the OS2®-C Compression Staple.

- Material: The OS2®-C Compression Staple are manufactured from the same raw material when compared to the Smith and Nephew Bioraptor 2.3 PK suture anchor (K071586) and meet appropriate ASTM standard.
 - Equivalent size range: The OS2®-C Compression Staple has similar range size when compared to the Biotech International Eleos Memory Staple (K112794), Integra / Newdeal UNI-CLIP (K011716) and Memometal Easyclip (K070031).
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Substantial Equivalence Summary

The OS2®-C Compression Staple intended use, design, material, technological characteristics and principles of operation are substantially equivalent to those of predicate devices, if applicable. The OS2®-C Compression Staple has similar mechanical properties when compared to the Biotech International Eleos Memory Staple (K112794).

Summary Performance Data

Performance assessment for the OS2®-C Compression Staple was made through mechanical comparison with predicate devices, animal and clinical testing being considered not applicable. Mechanical testing for both OS2®-C Compression Staple and predicate device was performed according to ASTM F564-06. The OS2®-C Compression Staple is substantially equivalent to the predicate devices identified in the 510(k) submission.

CONCLUSION

Based on the evaluations performed, the design and indications of the OS2®-C Compression Staple are substantially equivalent to the predicate devices identified in the 510(k) submission. No new materials or processes are used in the development of this implant.

In addition, the results of the testing performed by the test laboratory indicated that the implants performed as expected for each test.

The OS2®-C Compression Staples are acceptable for the application.
