510(k) Summary

MAY 3 2013

Date Prepared: December 19, 2012

Sponsor:
Metasurg
15115 Park Row, Suite 100
Houston, TX 77084

Company Contact:
Joshua Scott
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Device Trade Name: Metasurg Nitinol Staple Implant

Classification Name: Single/Multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030, Product Code JDR, Class II)

Common Name: Bone Staple

Predicate Devices:
Memometal Memory Staples (K070031)
Biomedical Enterprises, Inc. Memograph Staple (K993714)

Device Description: The Metasurg Nitinol Staple Implant is a one piece single use nickel titanium alloy bone fixation device intended to be permanently implanted. The device is indicated for the fixation of osteotomies and joint arthrodesis of the hands and feet. The implant consists of two legs connected by a bridge and is offered in multiple combinations of bridge widths and leg lengths to accommodate various anatomies.

Intended Usage: The Metasurg Nitinol Staple implant is indicated for fixation and arthrodesis of the associated bones and joints of the hands and feet.

The Metasurg Nitinol Staple implants are intended for single use only.

Material: Nickel Titanium Alloy (Nitinol) per ASTM F2063-05

Technological Characteristics: The Metasurg Nitinol Staple implant and the other legally marketed predicate devices listed in this summary have similar indications, physical dimensions and are constructed of nickel titanium alloy (Nitinol).

Substantial Equivalence: A design, dimensional comparison and standardized tests were performed to establish substantial equivalence in terms of intended use and indications for use, material, design and function to the legally marketed predicate devices listed in this summary.

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 3, 2013

Metasurg
% Mr. Joshua Scott
Vice President of Engineering
15115 Park Row, Suite 100
Houston, Texas 77084

Re: K123926
Trade/Device Name: Metasurg Nitinol Staple Implant
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: April 19, 2013
Received: April 22, 2013

Dear Mr. Scott:

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,

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: ~~Pending~~ K123926

Device Name: *Metasurg Nitinol Staple Implant*

Indications for Use:

The Metasurg Nitinol Staple implant is indicated for fixation and arthrodesis of the associated bones and joints of the hands and feet.

The Metasurg Nitinol Staple implants are intended for single use only.

Prescription Use __√__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices