**510(k) Summary**

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| Proprietary Name: | Easy Clip |
| Common Name: | Staple, Fixation, Bone |
| Classification Name and Reference: | Single/multiple component metallic bone fixation appliances and accessories 21 CFR §888.3030 |
| Regulatory Class: | Class II |
| Product Codes: | 87 JDR- Single/multiple component metallic bone fixation appliances and accessories |
| For Information contact: | Estela Celi, Regulatory Affairs Specialist<br>Stryker Trauma AG<br><br>Phone: (201) 831-6461 Fax:# (201) 831-3461 |
| Date Prepared: | July 16,2012 |

**Description:**
This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market Easy Clip. Additional sizes to the existing range and modifications are being made existing cleared 'Easy Clip' devices (K070031).

**Intended Use:**
The MEMORY METAL STAPLES (MEMOCLIP, EASYCLIP, and FOR FUSION) are indicated for hand and foot bone fragments osteotomy fixation and joint arthrodesis.

**Indications:**
The MEMORY METAL STAPLES (MEMOCLIP, EASYCLIP, and FOR FUSION) are indicated for hand and foot bone fragments osteotomy fixation and joint arthrodesis.

**Summary of Technologies:**
Device comparison showed that the proposed device is substantially equivalent in intended, use, materials and performance characteristics to the following predicate devices:

- K070031 – Memometal Memory Staples

**Non-Clinical Testing:**
Dimensional (geometric cross section) and engineering strength analyses as well as static and dynamic bending tests were conducted and the results support the conclusion that there are no effects of the modifications subject to this premarket notification on the safety and effectiveness of the EasyClip staples. Corrosion Testing as per ASTM F2129 was also performed.

**Clinical Testing:** Clinical testing was not required for this submission.

**Conclusion:** The additional Easy Clip staples are substantially equivalent to the predicate devices identified in this premarket notification.

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

Stryker, Corporation
% Ms. Estela Celi
Regulatory Affairs Specialist
132 Corporate Drive
Mahwah, New Jersey 07430

Letter dated: March 12, 2013

Re: K122113
Trade/Device Name: Memory Metal Staples
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: JDR
Dated: February 25, 2013
Received: February 26, 2013

Dear Ms. Celi:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 -S

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

Enclosure

## Indications for Use

510(k) Number (if known): K122113

Device Name: Memory Metal Staples

Indications for Use:

The MEMORY METAL STAPLES (MEMOCLIP, EASYCLIP, and FOR FUSION) are indicated for hand and foot bone fragments osteotomy fixation and joint arthrodesis.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopaedic Devices