SECTION 5: 510(K) SUMMARY

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

MAR 2 1 2007

As required by section 807.92(c)

Submitter	MEMOMETAL TECHNOLOGIES Campus de Ker Lann - Rue Blaise Pascal 35170 BRUZ – France Phone : + 33 (0)2 99 05 59 69 Fax :+ 33 (0)2 99 05 95 62
Contacts	Gilles AUDIC Quality Manager Bernard PRANDI General Manager e-mail: gilles.audic@memometal.com bernard.prandi@memometal.com
Preparation date	December 19, 2006
Trade Name	MEMOMETAL FIXOS Screws (S-Fix / C-Fix / P-Fix & W-Fix)
Common Name	FIXOS Screws
Classification Name	Screw, Fixation, Bone
Legally marketed predicate devices	K962233 LANDOS twist-off screw (LANDOS acquired by DEPUY Inc). K962236 LANDOS Scarf thread-head screw (LANDOS acquired by DEPUY Inc)
Description	MEMOMETAL FIXOS SCREWS are single-use bone fixation appliances intended to be permanently implanted. Screws are cannulated compressive screws made of titanium alloy (Ti – 6Al –4V ELI) and snap-off screws made of titanium alloy (alloy (Ti – 6Al –4V ELI)

Intended Use & Indication for use	The MEMOMETAL FIXOS Screws (S-Fix / C-Fix / P-Fix & W-FIX) are indicated for fixing and stabilizing the elective osteotomies of the mid-foot bones and the metatarsal and phalanges of the foot only.
Performance data	The MEMOMETAL FIXOS Screws (S-Fix / C-Fix / P-Fix & W-FIX) conform to ASTM F543-02 Standard Specification and Test Methods for Metallic Bone screw (Section A1, A2 and A3) and to ISO 5832-3 Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.
Substantial equivalence	THE MEMOMETAL FIXOS Screws (S-Fix / C-Fix / P-Fix & W-FIX) are substantially equivalent to their predicate devices LANDOS CANNULATED BONE SCREW and TWIST-OFF SCREW in terms of intended use and indications for use, material, design and function. Any minor differences between these two devices do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Memometal Technologies
% Mr. Gilles Audic
Quality Manager
Rue Blaise Pascal
Campus De Kerr Lann
Bruz, France F35170

MAR 2 1 2007

Re: K070039
Trade/Device Name: Memometal Fixos Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: December 28, 2006
Received: January 03, 2007

Dear Mr. Audic:

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.

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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K070039

Device Name: MEMOMETAL FIXOS® SCREWS

Indications for Use:

- The MEMOMETAL FIXOS Screws (S-Fix / C-Fix / P-Fix & W-Fix) are indicated for fixing and stabilizing the elective osteotomies of the mid-foot bones and the metatarsal and phalanges of the foot only.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brehm

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

510(k) Number K070039