K102072

SECTION 5: 510(K) SUMMARY

NOV - 3 2010

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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 50 66 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	07/19/2010
Trade Name	MEMOMETAL Implants (K-Snap® & Ti-Fuse®)
Common Name	MEMOMETAL implants
Classification Name	Smooth or threaded metallic bone fastener
Product code	HTY
Legally marketed predicate devices	K100736 SMT Schilling Metalltechnik GMBH Kirschner and Guide wire K022599 Newdeal K-Wire
Description	MEMOMETAL implants are single-use bone fixation appliances intended to be permanently implanted. MEMOMETAL implants are available in 2 different designs: - Snap-off pin, smooth with a stop and a sharp self drilling tip - Notched with a T-shaped head.
Intended Use	The MEMOMETAL implants (K-Snap® & Ti-Fuse®) are indicated for fixation of bone fracture, for bone reconstruction or arthrodesis in presence of appropriate immobilization. The size of the implant should be adapted to the specific indication.
Performance data	Engeneering rationale containing a comparison of mechanical

	properties of Ti-Fuse® and K-Snap® implants K100736 SMT Schilling Metalltechnik GMBH Kirschner and Guide wire under flexure loading (typical mechanical solicitation of the implants during the osteosynthesis period) has been performed. K-Snap® insertion testing in cortical bone has been performed to demonstrate that premature breakage doesn't occur.
Substantial equivalence	The MEMOMETAL implants (K-Snap® & Ti-Fuse®) are substantially equivalent to their predicate (K100736) SMT Schilling Metalltechnik GMBH Kirschner and Guide wire and to Newdeal K-Wire (K022599) in terms of intended use, design and function. Any minor differences between these devices do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MEMOMETAL TECHNOLOGIES
% Mr. Gilles Audic
Quality Manager
Campus de Ker Lann – Rue Blaise Pascal
35170 BRUZ - France

NOV - 3 2010

Re: K102072
Trade/Device Name: MEMOMETAL osteosynthesis implants (K-Snap® & Ti-Fuse®)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fasteners
Regulatory Class: Class II
Product Code: HTY
Dated: September 3, 2010
Received: September 7, 2010

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. 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.

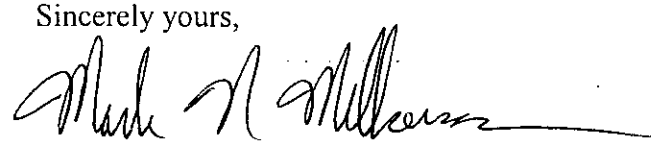
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

NOV - 3 2010

510(k) Number (if known): K102072

Device Name: MEMOMETAL osteosynthesis implants (K-Snap® & Ti-Fuse®)

Indications for Use:

The MEMOMETAL implants (K-Snap® & Ti-Fuse®) are indicated for fixation of bone fracture, for bone reconstruction or arthrodesis in presence of appropriate immobilization. The size of the implant should be adapted to the specific indication.

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

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102072