K112197 1/2

SECTION 5: 510(K) SUMMARY

NOV 17 2011

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
510K number	K070598
Preparation date	05/25/2011
Trade Name	MEMOMETAL INTRAMEDULLARY BONE FASTENER (SMART TOE / X-FUSE) new device designs
Common Name	INTRAMEDULLARY BONE FASTENER
Classification Name	Smooth or threaded metallic bone fastener
Legally marketed predicate devices	K070598 MEMOMETAL Intramedullary Bone Fastener Smart Toe & X-Fuse
Description	MEMOMETAL INTRAMEDULLARY MEMORY BONE FASTENER new device designs are single-use bone fixation appliances intended to be permanently implanted. Intramedullary memory bone fastener are a "double X-shape K-Wire" made of shape memory nickel titanium alloy.
Intended Use	The MEMOMETAL INTRAMEDULLARY BONE FASTENER (SMART TOE / X-FUSE) are indicated for small bone reconstruction limited to inter-digital fusion of fingers and toes and small bones fusion
Indication for use	The MEMOMETAL INTRAMEDULLARY BONE FASTENER (SMART TOE / X-FUSE) are indicated for small bone reconstruction limited to inter-digital fusion of fingers and toes and small bones fusion
Performance data	The MEMOMETAL INTRAMEDULLARY MEMORY BONE FASTENER (SMART TOE & X-FUSE) new device designs conform to ASTM F564-02 (2006) Standard Specification and

	Test Methods for Metallic Bone Staples and to ASTM F2063-05 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants.
Substantial equivalence	The MEMOMETAL INTRAMEDULLARY MEMORY BONE FASTENER (SMART TOE & X-FUSE) new device designs are substantially equivalent to their predicate device MEMOMETAL INTRAMEDULLARY MEMORY BONE FASTENER (SMART TOE & X-FUSE) (K070598) in terms of intended use and indications for use, design and function and in term of material. Any minor differences between these two devices do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

NOV 17 2011

Memometal Technologies
% Mr. Gilles Audic
Campus de Ker Lann – Rue Blaise Pascal
35170 BRUZ - France

Re: K112197
Trade/Device Name: Memometal Intramedullary Bone Fastener (Smart Toe & X-Fuse)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY
Dated: October 20, 2011
Received: October 20, 2011

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.

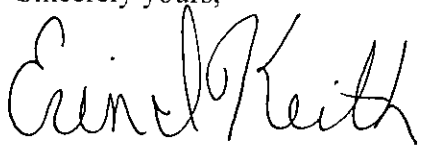
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

510(k) Number (if known): K112197

Device Name: MEMOMETAL INTRAMEDULLARY BONE FASTENER (SMART TOE & X-FUSE)

Indications for Use:

The MEMOMETAL INTRAMEDULLARY BONE FASTENER (SMART TOE / X-FUSE) are indicated for small bone reconstruction limited to inter-digital fusion of fingers and toes and small bones fusion

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)

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

510(k) Number K112197