K071941

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510k Premarket Notification Bone anchors MEMOMETAL TECHNOLOGIES	**Annexe 1bis**

SECTION 5: 510(K) SUMMARY

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	07/04/2007
Trade Name	MEMOMETAL Micro ARIM® anchor
Common Name	Bone Anchor
Classification Name	Smooth or threaded metallic bone fixation fastener.
Legally marketed predicate devices	K992487 MINI QUICKANCHOR PLUS (MITEK)
Description	MEMOMETAL Micro ARIM® anchors are single-use bone fixation appliances intended to be permanently implanted. Micro ARIM® anchors made of shape memory nickel titanium alloy. MEMOMETAL Micro ARIM anchors can be used in 2 versions with USP2-0 to USP 4-0 sutures (1 or 2 needles) listed below: Anchors Micro ARIM® th. 1mm – Length 3,8mm polyester suture (K012201) Anchors Micro ARIM® th. 1mm – Length 3,8mm Fiberwire suture (K041589) MEMOMETAL Micro ARIM® Anchors adopt an opened position after introducing into bone which allows a permanent fixation, thus supporting a secure ligament restoration.

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Indication for use	The MEMOMETAL Micro ARIM® is indicated for Hand: Ligament reconstruction Ankle: Midfoot reconstruction Foot: Hallux Valgus reconstruction Wrist: Scapholunate Ligament reconstruction Pubis: Fixation in the pubis for bladder neck suspension to resolve stress urinary incontinence
Performance data	THE MEMOMETAL Micro ARIM® conform to ASTM F2063-05 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants.
Substantial equivalence	THE MEMOMETAL Micro ARIM® are substantially equivalent to their predicate devices MITEK MiniQUICKANCHOR Plus 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

DEC 0 4 2007

Memometal Technologies
% Mr. Gilles Audic
Quality Manager/ Director
Campus de Ker Lann - Rue Blaise Pascal
Bruz, France F35170

Re: K071941
Trade/Device Name: Memometal Micro ARIM® anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, JDR, MBI
Dated: November 15, 2007
Received: November 16, 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

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

Enclosure

510k Premarket Notification bone anchors MEMOMETAL TECHNOLOGIES	

INDICATIONS FOR USE

510(k) Number (if known): K071941

Device Name: MEMOMETAL MICRO ARIM® BONE ANCHOR

Indications for Use:

The MEMOMETAL Micro ARIM® is indicated for

- Hand: ligament reconstruction
- Ankle: Midfoot reconstruction
- Foot: Hallux Valgus reconstruction
- Wrist: Scapholunate Ligament reconstruction
- Pubis: Fixation in the pubis for bladder neck suspension to resolve stress urinary incontinence

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use No (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 General, Restorative,
and Neurological Devices

510(k) Number K071941