K101930 1/3

510k Premarket Notification Navis® Bone Plating System MEMOMETAL TECHNOLOGIES	

MAR 15 2011

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 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	06/15/2010
Trade Name	Memometal Navis® Bone Plating System
Common Name	Memometal Navis® Bone Plating System
Class	II
Product Code	HRS HWC
CFR section	888.3030
Classification Name	Plate, Fixation, Bone Screw, Fixation, Bone
Legally marketed predicate devices	K051567 MEDARTIS, INC. APTUS® Titanium Fixation System K060041 TRIMED Bone plates K050512 & K060514 STRYKER variax® distal radius system
Description	MEMOMETAL Navis® Bone Plating System is single use bone fixation appliances intended to be permanently implanted. They are designed with anatomical shape plates made of biocompatible titanium alloy. The Bone Plating System use 2.5 mm locking, unlocking screws and 1.8 mm smooth locking pegs. The drill holes of the plates are aligned to assure the screws do not touch. The plates vary essentially through

510k Premarket Notification Navis® Bone Plating System MEMOMETAL TECHNOLOGIES	

	different lengths , widths, number of plate holes, left and right shapes.
Intended Use & Indication for use	The Navis® radius Plate is indicated for the fixation of fractures and osteotomies involving the distal radius.
Performance data	No clinical tests were used in the claim of substantial equivalence. Mechanical characterization of plates including 3 points bending test have been performed to demonstrate equivalence between Memometal Navis® bone plate system (K101930) and Aptus® Medartis bone plate system (K051567). The test was processed in accordance with the ASTM F382-99 standard. Additionally a characterization of the bending resistance of Memometal Navis® plates (K101930) and Medartis Aptus® plates (K051567) in bending loading conditions has been performed. An engeneering rationale containing a comparison of mechanical properties bending strength between Memometal Navis® Pegs (K101930) and Trimed pegs (K060041) has been performed. Mechanical characterization of pegs back out resistance on plates has been performed to demonstrate equivalence between Memometal Navis® bone plate system (K101930) and STRYKER variax® distal radius system (K050512 & K060514) All these tests demonstrate substantial equivalence between the Navis® bone plating system and their predicate devices. For this reason we didn't consider pre clinical data necessary.
Substantial equivalence	The MEMOMETAL Navis® Bone Plating Systems are substantially equivalent to their predicate MEDARTIS, INC. APTUS® Titanium Fixation System (K051567) for the plates and screws in terms of intended use and indications for use, material, design (thickness, length, number of holes) and

510k Premarket Notification Navis® Bone Plating System MEMOMETAL TECHNOLOGIES	

	function, and to TRIMED Bone plates (K060041) & STRYKER variax® distal radius system (K050512 & K060514) for Pegs in terms material, design (diameter, length), mechanical characteristics (back out and bending strength) and function. Any minor differences between these 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

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

MAR 15 2011

Re: K101930
Trade/Device Name: Memometal Navis Bone Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: March 1, 2011
Received: March 7, 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

510k Premarket Notification Navis® Bone Plating System MEMOMETAL TECHNOLOGIES	

INDICATIONS FOR USE

510(k) Number (if known): K101930

Device Name: MEMOMETAL Navis® Bone Plating System

Indications for Use:

- The Navis® radius Plate is indicated for the fixation of fractures and osteotomies involving the distal radius.

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)

for M. Melkerson

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

510(k) Number K101930