K023486

APPENDIX IV (510(k) Summary)

OCT 31 2002

Product: BioWarm™

BioMedical Enterprises, Inc. (BME) intends to introduce a device modification to the original approved Warmsystem to heat shape memory Nitinol staples (the "OSStaple™") to achieve compression.

a. Submittor Information

BioMedical Enterprises, Inc.
14785 Omicron Drive, Ste. 205
San Antonio, Texas 78245
Telephone: (210) 677-0354
Contact: Dr. W. Casey Fox (President)

Date Prepared: September 25, 2002

b. Classification name: Staple, Fixation, Bone
Common/Usual Name: Bone staple
Proprietary Name: OSStaple™, BioWarm™

c. Intended Use:

Original indications for the Memograph® Staple System are as defined in 510(k) K993714. Additional indications fro the OSStaple™ are the fixation of maxillofacial and mandibulofacial fractures and osteotomies.

d. Device Description

The BioWarm™ represents a modification to the Warmsystem currently in use with the OSStaple™ bone staple system. The BioWarm™ has an on/off switch and two user adjusted controls. A user adjusted current and user adjusted time controls are on the front of the console. The controls are set to the requirements of a specific staple size and configuration. The BioWarm™ gives both visual and audible indications of current delivery and an audible signal upon automatic completion of current delivery. The BioWarm™, on the electrode handle, also provides visual indication of positive contact between the electrode and staple to be heated and visual indication of actual current flow. Current is activated with a button switch on the handle of the BioWarm™ electrode and will cease if the button is released prior to the automatic cessation by the circuitry

e. Substantial Equivalence:

The Warmsystem heating unit was approved via 510(k)s K993714, 001219, 001353 and 001354 and no fundamental technology changes are represented with the BioWarm™ modification.

(Signature)

W. Casey Fox, Ph.D. P.E.
President
BioMedical Enterprises, Inc.

10/14/02
(Date)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2002

Dr. W. Casey Fox
President
BioMedical Enterprises, Incorporated
14785 Omicron Drive, Suite 205
San Antonio, Texas 78245

Re: K023486
Trade/Device Name: Memograph® Staple System
Regulation Number: 872.4760 and 888.3030
Regulation Name: Bone Plate and Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class: II
Product Code: JEY and HRS
Dated: October 15, 2002
Received: October 17, 2002

Dear Dr. Fox:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K023486

APPENDIX III (Indication For Use)

Device Name: Memograph® Staple System

Original indications for the Memograph® Staple System are as defined in 510(k) K993714. Additional indications fro the OSStaple™ are the fixation of maxillofacial and mandibulofacial fractures and osteotomies.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K023486