

FEB 25 2000

K993714

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APPENDIX III  
510(k) Summary

**Product:** Memograph® Staple System

BioMedical Enterprises, Inc. (BME) intends to introduce into commercial distribution the Memograph® Staple System consisting of shape memory Nitinol staples and accessories for setting and warming the staples to achieve compression.

a. Submitter 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: January 25, 2000

b. Classification name: Staple, Fixation, Bone

Common/Usual Name: Bone staple

Proprietary Name: Memograph® Staple System

c. Intended Use:

The Memograph® Staple is intended for:

1) hand and foot bone fragment and osteotomy fixation and joint arthrodesis, 2) fixation of proximal tibial metaphysis osteotomy and 3) fixation of soft tissue to bone such as anterior cruciate reconstruction.

d. Device Description

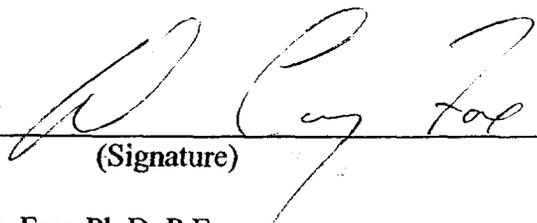
The Memograph® Staple system consists of two and four prong staples for 1) hand and foot bone fragment and osteotomy fixation and joint arthrodesis, 2) fixation of proximal tibial metaphysis osteotomy and 3) fixation of soft tissue to bone such as in anterior cruciate ligament reconstruction. The staple is fabricated from Nitinol. The staple's prongs are parallel during insertion. Application of an electrical current from the Warmsystem to the staple causes its prong to deflect inward. This inward deflection causes staple retention and compression across the osteotomy or arthrodesis site.

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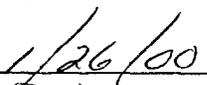
e. Substantial Equivalence:

The Memograph® Staple System is substantially equivalent to devices as described below. The FDA has classified these equivalent devices as Class II devices (e.g. 21 CFR 878.4400, 4750 and 886-4115). The Memograph® Staple System is a Class II medical device.

The Memograph® Staple is substantially equivalent to the Memory Staple™ (510(k) 964226). The Memory Staple™ and the Memograph® Staple use a shape memory material (Nitinol) to achieve compression when heat allows the material to return to its stable configuration. The Memograph® Staple is also substantially equivalent to the Zimmer Epiphyseal and Fracture staples and Smith & Nephew's Richard's Regular Fixation Staple. The Warmsystem heating unit is substantially equivalent to the Hemostatic Surgical System (K902307) by Hemostatic surgery Corporation and the Accu-Temp surgical cautery device (preamendment) by Concept, Inc. These predicate devices use the joule (heating) effect of electrical current in a conductor to increase the temperature of the conductor to cauterize or cut tissue. The Warmsystem uses the same effect to increase the temperature of the Nitinol staple (as the conductor) allowing it to return to its stable position thereby causing compression. Internal circuitry controls the heating effect and tissue damage by limiting current and time such that a limiting temperature of 55°C is achieved in a maximum of 5 seconds.

  
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(Signature)

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

  
\_\_\_\_\_  
(Date)



FEB 25 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. W. Casey Fox, Ph.D., P.E.  
President  
Biomedical Enterprises, Inc.  
14785 Omicron Drive, Suite 205  
San Antonio, Texas 78245

Re: K993714  
Trade Name: Memograph® Staple System  
Regulatory Class: II  
Product Code: JDR  
Dated: December 14, 1999  
Received: December 16, 1999

Dear Mr. Fox:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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.

Page 2 – Mr. W. Casey Fox, Ph.D., P.E.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



*for* James E. Dillard III  
Acting Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**APPENDIX II**  
**Indication For Use**

Device Name: Memograph® Staple System

Indications for use: The Memograph® Staple is intended for:

1) hand and foot bone fragment and osteotomy fixation and joint arthrodesis, 2) fixation of proximal tibial metaphysis osteotomy, and 3) fixation of soft tissue to bone such as anterior cruciate reconstruction.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K 993714  
K 993714

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)