

K964226

SUMMARY OF SAFETY AND EFFECTIVENESS

AUG - 5 1997

MANUFACTURER IDENTIFICATION: Medinov-AMP
27 à 31 rue Lucien Langenieux
42335 Roanne FRANCE

ESTABLISHMENT REGISTRATION NUMBER (Manufacturer): 9681744

SPONSOR IDENTIFICATION: Cheryl Hastings
DePuy, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, IN 46580

ESTABLISHMENT REGISTRATION NUMBER (Sponsor): 1818910

PROPRIETARY NAME: Memory Staple™

PRODUCT CLASSIFICATION CODE: 87JDR

PROPOSED REGULATORY CLASS: Class II

DESCRIPTION:

The **Memory Staple** is a single use bone fixation appliance intended to be permanently implanted. It is a bicortical compression staple made of a shape memory Nickel-Titanium alloy.

INTENDED USE AND INDICATIONS:

The **Memory Staple** is intended for bone fixation for the indications of osteotomies and arthrodeses of the mid-foot bones, the metatarsals, the phalanges, and associated joints of the foot.

PREDICATE DEVICES:

The **Memory Staple** is substantially equivalent to:

- 1) The Landos Standard Staple
- 2) The Stryker Osteoclasp
- 3) The Mitek Anchor II™

BASIS OF SUBSTANTIAL EQUIVALENCE:

The **Memory Staple**, the **Landos Standard Staple** and the **Stryker Osteoclasp** are all intended for bone fixation. The **Memory Staple** and the **Mitek Anchor II** are both manufactured from Nickel-Titanium shape memory alloy.

SUMMARY OF STUDIES:

Prong separation tests were performed on the **Memory Staple** and the **Landos Standard Staple**. The results showed that the **Memory Staple** had more than twice the strength of the **Landos Standard Staple**. Successful clinical use of the **Memory Staple** in 315 osteotomies of the great toe between 1991-1994 was reported by Barouk in 1994.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Cheryl Hastings
Manager Clinical Affairs
DePuy, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

AUG - 5 1997

Re: K964226
Trade Name: Memory Staple
Regulatory Class: II
Product Code: JDR
Dated: May 30, 1997
Received: June 2, 1997

Dear Ms. Hastings:

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.

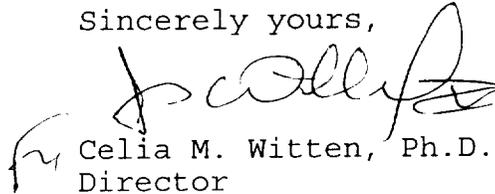
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

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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.

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) 594-4659. 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C".

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K964226

Device Name: Memory Staple™

CONFIDENTIAL

Indications For Use:

For Fixing the osteotomies and arthrodesis of the mid foot bones, the metatarsals, the phalanges, and associated joints of the foot.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K964226

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)