

K971068

SUMMARY OF SAFETY AND EFFECTIVENESS

MANUFACTURER IDENTIFICATION:

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

JUL - 9 1997

**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:

34mm SCARF Thread-Head Screw

PRODUCT CLASSIFICATION CODE:

87HWC

PROPOSED REGULATORY CLASS:

Class II

DESCRIPTION:

The 34mm SCARF Thread-Head Screw is a threaded bone fixation screw that is 3.0mm in diameter and 34mm in length. It is made of titanium alloy and is cannulated with a threaded head. This screw is an extension of the product line for the SCARF Thread-Head Screw.

INDICATIONS AND INTENDED USE:

This screw is to be implanted for the fixation of fractures, fusion of a joint or bone reconstruction of the mid-foot, metatarsals and phalanges of the foot.

PREDICATE DEVICES:

The predicate devices for this screw are the Landos SCARF Thread-Head Screw, the Zimmer Herbert-Whipple Bone Screw and the Osteomed M3 Screw.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL - 9 1997

Re: K971068
34mm SCARF Thread-Head™ Screw
Regulatory Class: II
Product Code: HWC
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.

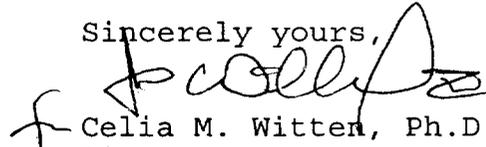
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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 at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


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): K971068

Device Name: 34mm Thread-Head Screw

Indications for Use:

Fixation of fracture, fusion of a joint or bone reconstruction (osteotomy) of the mid-foot, metatarsals and phalanges of the foot.

CONFIDENTIAL

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Chief)
Division of Restorative Devices
510(k) Number K971068

Prescription Use (Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)