

510(k) Summary

FEB 12 1998

Device: Epi-Union Plating System

K9 74289

For information contact: Vivian Kelly  
Manager, Regulatory Affairs  
Howmedica Inc.  
359 Veterans Boulevard  
Rutherford, NJ 07070  
(201) 507-7830  
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The Epi-Union Plating System consists of a series of plates and screws for the internal fixation of long bone fractures and long bone reconstruction. The plates are available in different styles and configurations to fit various anatomical sites. Each plate has holes for screw fixation. The different styles of plates are precontoured to fit the anatomical profile of each specific site. The system includes tibial plates, fibular plates, calcaneal plates, humeral plates, and radial plates.

The system includes cancellous and cortical screws with head diameters of 6mm and 8mm. The screws are available in thread diameters ranging from 3.5mm to 6.5mm in varying lengths. Different styles include self-tapping, non-self-tapping, fully threaded, and partially threaded screw designs. The plates can also be used with standard cortical or cancellous bone screws that are commercially distributed.

The substantial equivalence of these components is based on an equivalence in intended use, materials, design, and operational principles to other predicate devices used for internal fixation of long bones. These devices include Synthes' ASIF® Implants, the Dupont Distal Humeral Plate System and BG Compression System distributed by Howmedica Inc.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 12 1998

Ms. Vivian Kelly  
Manager, Regulatory Affairs  
Howmedica, Inc.  
359 Veterans Boulevard  
Rutherford, New Jersey 07070-2584

Re: K974289  
EPI-UNION Plating System  
Regulatory Class: II  
Product Code: HRS and HWC  
Dated: November 14, 1997  
Received: November 14, 1997

Dear Ms. Kelly:

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. Note that labeling or otherwise promoting a device for pedicular screw fixation/attachment would cause the device to be adulterated under 501(f)(1) of the Act. This device, if intended for use in pedicular screw fixation/attachment, would be found not substantially equivalent and would be a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. The package insert must prominently state that the device is intended for the specific use(s) described in the enclosure only; and

2. You may not label or in any way promote this device for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. If this device is a screw with outer diameters of 3 mm - 10 mm and overall lengths of 10 mm - 75 mm inclusively, the package insert must include the following statement, "**WARNING:** This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine." Any pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conduct of the investigation.

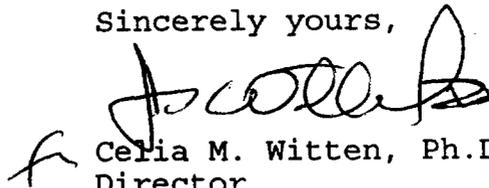
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

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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,



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

Indications for Use

510(k) Number (if known): K974289

Device Name: EPI-UNION™ PLATING SYSTEM

Indications for Use:

The EPI-Union Plating System is intended for use in the internal fixation of long bone fractures and long bone reconstruction.

Prescription Use \_\_\_\_\_  
(per 21 CFR 801.109)

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\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices

510(k) Number K974289

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