

K973586

Spinal Concepts, Inc.  
 Universal Bone Plate (UBP) System II Pre-market Notification  
 September 18, 1997

**SUMMARY OF SAFETY AND EFFECTIVENESS  
 UNIVERSAL BONE PLATE SYSTEM II  
 (TITANIUM)**

**I. General Information**

NOV - 7 1997

**Classification Name:** Single/multiple component metallic bone fixation appliances and accessories.

**Common Name:** Titanium Bone Plate and Screws

**Device Trade Name:** Universal Bone Plate (UBP) System II

**Classification Code:** 87HRS  
 87HWC

**Submitter's Name & Address:** Spinal Concepts, Inc.  
 8200 Cameron Road, Suite B-160  
 Austin, Texas 78754 U.S.A.  
 (512) 339-4800

**Establishment Registration No:** 1649384

**Contact Person:**  
 Teena M. Augustino  
 Director, Clinical and Regulatory Affairs

**Summary Preparation Date:** September 18, 1997

**II. Predicate Device**

The Spinal Concepts, Inc. Universal Bone Plate (UBP) System II is claimed to be substantially equivalent in material, design, and function to the existing UBP System.

**III. Device Description**

The UBP System II is intended bring together bone fragments in order to augment fracture healing of the small bones of the foot, wrist and hand. The UBP System II consists of canted, variable-distance multi-hole bone plates, cortical and cancellous screws, and instrumentation. The UBP System II instrumentation set consists of the standard instrumentation required for each indicated procedure. Implants are for single use only.

**IV. Sterilization**

UBP System II implants and instrumentation may be provided sterile or non-sterile. Both implants and instruments must be sterilized prior to use in accordance with the recommended sterilization parameters described in the package insert in order to achieve a sterility assurance level of  $10^{-6}$ .

**V. Indications for Use**

The UBP System II is indicated as a means to bring together bone fragments in order to augment fracture healing of the small bones of the foot, wrist and hand.

**VI. Substantial Equivalence**

The UBP System II is considered to be substantially equivalent to the existing UBP System.

<b>Technological Comparison of Devices</b>		
	<b>UBP System II Implants</b>	<b>UBP System Implants (Original/Predicate)</b>
<b>Material</b>	Titanium 6AL- 4V	Titanium 6AL- 4V
<b>Design</b>	Canted, variable distance, multi-hole bone plates. Cortical and cancellous bone screws in a range of sizes. Radiused, reduced cross-sectional profile height.	Non-canted, fixed-distance, multi-hole bone plates.  Bone screw with a single threaded profile.  Non-radiused cross-sectional profile height.
<b>Function</b>	To bring together bone fragments in order to augment fracture healing.	To bring together bone fragments in order to augment fracture healing.
<b>Indication</b>	To bring together bone fragments in order to augment fracture healing of the small bones of the foot, wrist and hand.	To bring together bone fragments in order to augment fracture healing of the small bones of the foot, wrist and hand.

**VII. Mechanical Testing**

Static and fatigue testing was performed on the UBP System II bone plates and the existing, commercially available UBP bone plates. These data were compared with published data of various bone plates used for long bone fixation. The results of this testing demonstrated the UBP System II bone plate to be substantially equivalent to the existing UBP System bone plate, and able to withstand clinical loading and maintain mechanical integrity.

**VIII. Conclusion**

The UBP System II is considered to be substantially equivalent in design, material and function to the existing UBP System. The results of mechanical testing demonstrate that the UBP System II bone plate is equivalent in static and fatigue performance to the existing UBP System bone plate. The UBP System II is believed to perform as well as or better than the existing UBP System.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV - 7 1997

Ms. Teena M. Augustino  
Director, Regulatory and Clinical Affairs  
Spinal Concepts, Inc.  
8200 Cameron Road, Suite B-160  
Austin, Texas 78754

Re: K973586  
Universal Bone Plate (UBP) System II  
Regulatory Class: II  
Product Codes: HWC and HRS  
Dated: September 18, 1997  
Received: September 22, 1997

Dear Ms. Augustino:

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

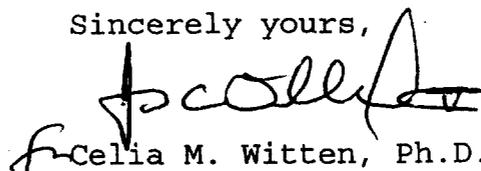
2. You may not label or in any way promote this device for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. If this device is a screw with outer diameters of 3 mm - 10 mm and overall lengths of 10 mm - 75 mm inclusively, the package insert must include 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.

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

INDICATION FOR USE STATEMENT

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510(k) Number (if known): K973586

Device Name: Universal Bone Plate (UBP) System II

Indications for Use: The Universal Bone Plate (UBP) System II is intended to bring together bone fragments in order to augment fracture healing of the small bones of the foot, wrist and hand.

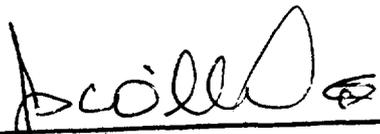
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:   
(Per 21 CFR 801.109)

Or

Over-The-Counter \_\_\_\_\_  
(Optional Format 1-2-96)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K973586