K011460

AUG - 7 2001

510(k) Summary

Submitted By: BioPro, Inc.
17 17th Street
Port Huron, MI 48060

Contact: Patrick Pringle
(810) 987-7777 Fax: (810) 982-7794 Email pat@advnet.net

Device Information:

Proprietary name: Wujin #3 Tibial Bone Plate
Common name: Single/multiple component metallic bone fixation appliances and accessories
Classification name: Single/multiple component metallic bone fixation appliances and accessories

Wujin #3 Tibial Bone Plate:

The Wujin #3 Tibial Bone Plate will be available in two material options: it can be manufactured from either Stainless Steel (ASTM F 138) or Titanium Ti-6Al-4V (ASTM F 1472). The Wujin #3 Tibial Bone Plate (manufactured from Stainless Steel) will be available in a 4 thru 26 hole options in 2 hole increments (item numbers: 16515-16520, 16764-16769) and is to be used in conjunction with Stainless Steel (ASTM F 138) screws. The Wujin #3 Tibial Bone Plate (manufactured from Titanium) will be available in a 4 thru 26 hole options in 2 hole increments (item numbers: 16508,16399-16401, 16509,16510, 16770-16775) and is to be used in conjunction with Titanium Ti-6Al-4V ELI (ASTM F 136) screws.

Substantial Equivalence:

The Wujin #3 Tibial Bone Plate is substantially equivalent to the Smith + Nephew 4.5mm Narrow Compression Plate. See Appendix B for more information on the Smith + Nephew 4.5mm Narrow Compression Plate. Both styles are to be used in conjunction with a number of threaded bone screws (depending on the number of holes the plate possesses). Also, in both the styles these holes are oval in shape and are offset from one another. The Wujin #3 Bone Plate is available in either Titanium or Stainless Steel, while the Smith + Nephew 4.5mm Narrow Compression Plate is only available in Stainless Steel. The Wujin #3 Tibial Bone Plate has a 4 thru 26 hole option in 2 hole increments. The Smith + Nephew 4.5mm Narrow Compression Plate, however, is available in a 2 thru 16 hole option in 1 hole increments and 18 thru 24 in 2 hole options.

Although there are minor differences between the Wujin #3 Tibial Bone Plate and the Smith + Nephew 4.5mm Narrow Compression Plate, they are substantially equivalent in form and function. Both systems are indicated for short and long fractures of the tibia.

Comparison of Wujin #3 Tibial Bone Plate
vs. The Smith + Nephew 4.5mm Narrow Compression Plate

Similarities

1) Used for short or long fractures of the tibia

2) To be used in conjunction with a threaded bone screw

3) Possesses oval holes that are offset from one another

4) Both are similar in size and shape

Differences

1) The Wujin #3 Tibial Bone Plate has a 4 thru 26 hole option in 2 hole increments. The Smith + Nephew 4.5mm Narrow Compression Plate, however, is available in a 2 thru 16 hole option in 1 hole increments and 18 thru 24 in 2 hole options.

2) The Wujin #3- Is available in either Titanium or Stainless Steel
   The Smith + Nephew- Is available in Stainless Steel

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2001

Mr. Patrick Pringle
Chief Executive Officer
BioPro, Inc.
17 Seventeenth Street
Port Huron, Michigan 48060

Re: K011460
Trade/Device Name: Wujin #3 Tibial Bone Plate
Regulation Number: 888.3030, 888.3040
Regulatory Class: II
Product Code: HRS, HWC
Dated: May 9, 2001
Received: May 11, 2001

Dear Mr. Pringle:

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 legally marketed predicate 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 requirements, 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

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

Enclosure

510(k) Number (if known):

Device Name: Wujin #3 Tibial Bone Plate

Indications For Use:

1) Short tibial fractures

2) Long tibial fractures

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

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011460

Prescription Use OR Over-The Counter
Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)