

OCT 19 1998

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## SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR: Biomet, Inc. Contact Person:  
Airport Industrial Park Julie K. Ryan  
Warsaw, Indiana 46580

PROPIETARY NAME: BMP™ Cable System

COMMON OR USUAL NAME: Metallic Internal Fixation Devices  
Cerclage Cable System

CLASSIFICATION NAME: Bone, fixation Cerclage 888.3010  
Plate, Fixation, Bone 888.3030

DEVICE CLASSIFICATION: Class II

DEVICE PRODUCT CODE: 87 JDQ

INTENDED USE: The BMP™ Cable System is indicated for general orthopedic repairs. This includes such procedures as long bone fractures, bone grafting, reinforcement of bone and reattachment of the greater trochanter.

DESCRIPTION OF DEVICE: The BMP™ Cable System consists of cables, cable sleeves, trochanteric grip, cable plates and cable templates. The system also includes lateral trochanteric plates and supercondylar plates. The cables and cable sleeves are made of either cobalt chrome or stainless steel. All cables are 7x7 construction. Seven individual wires form a bundle and seven bundles are combined to form each cable optimizing strength and flexibility. The cobalt chrome is available in 2.0mm and 1.6mm diameter cables to be used with titanium and cobalt chrome implants. The stainless steel cables are 2.0mm diameter and used with stainless steel implant and the BMP cable plates. Three sleeves are available: 2.0mm CoCr, 1.6mm CoCr and 2.0mm stainless steel.

The trochanteric grips are cobalt chrome and are available in two sizes – medium and large. Each grip has two crimp locations and do not require additional sleeves. The holes on the tronchateric grip are full radius.

The cable plates are available in five lengths from 110mm to 310mm. Each plate is a one piece plate and sleeve construction manufactures from 316 LVM stainless steel. The one-piece construction allows for the sleeves to be machined directly on each plate, thus eliminating micromotion between the plate and sleeves. Stainless steel cable and screws are used to attach these plates to bone. The system includes templates for the corresponding plate size. A smaller plate for use on the humerous is being planned.

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There are two specialty plates in the system. The supracondylar cable plate comes in two lengths, 165 mm and 241 mm. The plate is manufactured out of 316 LVM stainless steel. Stainless steel screws and cables are used to attach this plate to bone. The lateral trochanteric plate is a Co-Cr-Mo plate that is manufactured in one length – 185 mm. It is attached to the bone with titanium screws and Co-Cr- Mo cable.

Instruments for use with these devices include cable passers, crimper, standard trochanteric grip impactor, T- handle tensioner, cable cutters, trochanteric grip manipulator/impactor and sterilization case.

**POTENTIAL RISKS:** The potential risks associated with this device are the same as with any other cerclage system. These include but not limited to:

- Nonunion or delayed union
- Bending or fracture of the implant
- Metal sensitivity or allergic reaction to foreign body
- Limb shortening due to compression of fracture bone
- Bone resorption
- Decrease in bone density due to stress shielding
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma
- Necrosis of bone

**SUBSTANTIAL EQUIVALENCE:** The BMP™ Cable System is substantially equivalent to most cable/Cerclage system on the market in overall design and intended function.

Predicate devices include:

- Dall-Miles Cable System by Howmedica (K971741)
- Dall-Miles Trochanter Cable Grip System by Howmedica (K934058)
- Osteo-Clage Cable System by Acumed, Inc. (K921480)
- J-Fx Cerclage System by Johnson and Johnson (K971682)
- Epi-Union Plating System by Howmedica (K974289)
- Osteo-Anatomical bone Plates by Oestonics Corp.(K972196)

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Julie K. Ryan  
Regulatory Specialist  
Biomet, Inc.  
P.O. Box 587  
Warsaw, Indiana 46581-0587

Re: K982545  
Trade Name: BMP™ Cable System  
Regulatory Class: II  
Product Codes: JDQ and HRS  
Dated: July 17, 1998  
Received: July 21, 1998

Dear Ms. Ryan:

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.

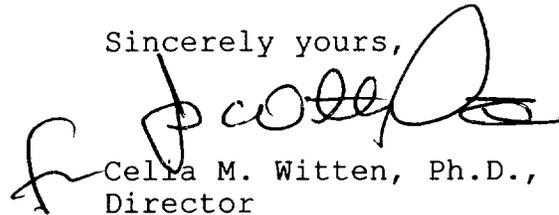
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,



Cella 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: K982545  
DEVICE NAME: BMP CABLE SYSTEM

Indications of Use:

There are several items that make up this system. They will be listed separately with their intended use:

Cable Implants:

- Femur and Tibial Fractures
- Prophylactic banding
- Trochanteric reattachment
- Olecranon fractures
- Patella fractures
- Ankle fractures
- Fixation of spiral fractures in conjunction with I/M nailing and screwing techniques.
- Sternum fixation after open chest surgery
- Stabilization of cortical onlay strut graft

Trochanteric Grip:

- Reattachment of greater trochanter following osteomy for total hip or total hip Procedures or trochanteric advancement

Cable Plates

- Fixation of femoral, tibial or humeral fractures near the site of an intramedullary implant
- Fixation of fractures where a combination of screws and cerclage cables would improve stabilization

Supracondylar Cable Plate

- Distal femoral fractures
- Subtrochanteric fractures

Lateral Trochanteric Plate

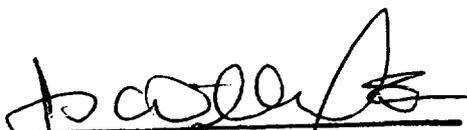
- Extended trochanteric osteomies
- Trochanteric fractures

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

or Over-the-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

  
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 (Division Sign-Off)  
 Division of General Restorative Devices  
 510(k) Number K982545