

JUN 25 1998

**Summary of Safety and Effectiveness Information**  
(for release on request only)

**Regulatory Authority:**

**Safe Medical Devices Act of 1990, 21 CFR 807.92**

**Company Name/Contact:**

**Company:** Cross Medical Products, Inc.  
5160 Blazer Memorial Parkway  
Suite A  
Dublin, Ohio 43017-1339  
(614)718-0530 FAX (614)718-0540

**Medical Device Establishment  
Registration Number: 1526354**

**Contact:** Regulatory Affairs Department  
Cross Medical Products, Inc.  
5160 Blazer Memorial Parkway  
Suite A  
Dublin, Ohio 43017-1339  
(614)718-0530 FAX (614)718-0540

**Device Name:**

**Trade Name:** Cross Medical Bone Plate System

**Common Name:** Bone Screws and Bone Plates

**Classification  
Name(s):** Screw, Fixation, Bone  
Plate, Fixation, Bone

**Registration Number:** 1526354

**Classification:**

“§ 888.3030 Single/multiple component metallic bone fixation appliances and accessories. (a) Identification. Single/multiple component metallic bone fixation appliances and accessories are devices intended to be implanted consisting of one or more metallic components and their metallic fasteners. The devices contain a plate, a nail/plate combination, or a blade/plate combination that are made of alloys, such as cobalt-chromium-molybdenum, stainless steel, and titanium, that are intended to be held in position with fasteners, such as screws and nails, or bolts, nuts, and washers. These devices are used for fixation of fractures of the proximal or distal end of long bones, such as intracapsular, intertrochanteric, intercervical, supracondylar, or condylar fractures of the femur; for fusion of a joint; or for surgical procedures that involve cutting a bone. The devices may be implanted or attached through the skin so that a pulling force (traction) may be applied to the skeletal system. (b) Classification. Class II.”

“§ 888.3040 Smooth or threaded metallic bone fixation fastener. (a) Identification. A smooth or threaded metallic bone fixation fastener is a device intended to be implanted that consists of a stiff wire segment or rod made of alloys, such as cobalt-chromium-molybdenum and stainless steel, and that may be smooth on the outside, fully or partially threaded, straight or U-shaped; and may be either blunt pointed, sharp pointed, or have a formed, slotted head on the end. It may be used for fixation of bone fractures, for bone reconstructions, as a guide pin for insertion of other implants, or it may be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system. (b) Classification. Class II.”

**Performance Standards:**

Food and Drug Administration developed performance standards applicable to the Cross Medical Bone Plate System do not exist. Until such time as Performance Standards are developed by FDA and published in the Federal Register, Cross Medical Products, Inc. intends to produce this device according to the regulations and standards that are appropriate to the risk that Class II devices reasonably present. Voluntary performance standards, such as vendor and materials certifications, in-house SOP's and ASTM Standards and/or ISO standards are utilized as appropriate.

**Substantially Equivalent Device(s):**

1. **Ace Brand Bone Plates and Screws**
2. **Synthes Brand Bone Plates and Screws**

**Device Description:**

3.5 mm x 8 mm Bone Screw through 3.5 mm x 30 mm Bone Screw in 2 mm increments

4.0 mm x 8 mm Bone Screw through 4.0 mm x 30 mm Bone Screw in 2 mm increments

C-Plates Assorted Sizes

**Instrumentation:**

Device specific instrumentation is necessary for the insertion and anchoring of the CM Bone Plate System. System instrumentation includes:

Plate Holder	Drill Bits
Plate Cutter	Driver Handle
Plate Bender	Screw Taps
Plate Shaper	Screwdriver
Plate Template	Screw Holder
Drill Guide	Sterilizer Case

The CM Bone Plate System instruments are made from stainless steel meeting ASTM F-899-84 and/or A276-91 standards. The instruments are simply standard manual orthopaedic surgical instruments ordinarily exempt from 510(k) Notification. They are offered for FDA review as accessories to this device system for the sake of completeness and are a part of this submission.

**Intended Use:**

The **Cross Medical Bone Plate System** is intended for non-spinal applications only in the treatment of internal fixation of pelvic fractures.

**Warning:**

This device is not approved for screw attachment for fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

**General.**

The implants of the new system are made from titanium alloy (6Al, 4V, ELI) and CP titanium or from 22-23-5 Stainless Steel.

The titanium bone plates are made from commercially pure titanium meeting ASTM F67-89. This material is also known as Commercially Pure Titanium (CP Ti, Grade 2). The stainless steel bone plates are made from ASTM F-1314, also known as 22-23-5 Stainless Steel.

The titanium bone screws are made from the industry standard alloy Ti 6Al-4V ELI, ASTM F-136-92. The stainless steel bone screws are made from ASTM F-1314, also known as 22-23-5 Stainless Steel.

The surface of both the titanium screws and titanium plates are anodized and/or matte finished. The surface of both the stainless steel screws and stainless steel plates are matte finished.

The CP titanium plates are offered for their ease of contouring and their mechanical performance.

**Contraindications and Cautions.**

The existence of the following conditions may complicate or contraindicate treatment using internal fixation: bony abnormalities preventing safe screw fixation, metal sensitivities, morbid obesity, severe osteopenia and localized infections at the site of fixation or other disseminated infections (septicemia).

In general, the CM Bone Plate System should only be implanted by surgeons fully experienced in the use of implants and the required specialized orthopaedic surgery techniques.

**Packaging:**

All packaging will be of a sufficient design and material quality to provide protection from physical damage during transportation and storage. Typical packaging used for such applications are medical grade peel packs, pouches, boxes or tubes.

**Sterilization/Resterilization:**

All instruments and implants are supplied **Non-Sterile**. Non-Sterile instruments and implants are packaged in "clear only" condition. The labeling of the implants & instruments clearly indicates their sterility status. The package insert found in Appendix I (labeling) contains a sterilization/resterilization guideline.

All packaging materials must be removed prior to sterilization. High temperature steam autoclave sterilization should be used, with the following cycle having been laboratory validated:

**Method:** Steam  
**Cycle:** Gravity  
**Temperature:** 250° F (121° C)  
**Exposure Time:** 30 minutes

**Note:** It is recommended to dry and/or cool the parts to prevent condensation after the steam cycle. Only sterile products should be used in the operative field.

The recommended sterilization cycle is based on HIMA/AORN protocols. Other sterilization methods and cycles may also be suitable. However, individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.

**Substantial Equivalence:**

The **Cross Medical™ Bone Plate System** is substantially equivalent to the Ace and Synthes brand bone plates and screws.

**Conclusion:**

Based on the basic design concept, the use of established well known materials, feature comparisons, mechanical testing,, indications for use, surgical approach, preproduction quality assurance planning and engineering analysis, Cross Medical Products, Inc. believes that sufficient evidence exists to reasonably conclude that this device is substantially equivalent to existing legally marketed bone plate and screw systems.



JUN 25 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Mark E. Apgar  
Project Engineer  
Cross Medical Products, Inc.  
5160-A Blazer Memorial Parkway  
Dublin, Ohio 43017-1339

Re: K961320  
Trade Name: Cross Medical Bone Plate System  
Regulatory Class: II  
Product Codes: HRS and HWC  
Dated: April 7, 1998  
Received: April 9, 1998

Dear Mr. Apgar:

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.

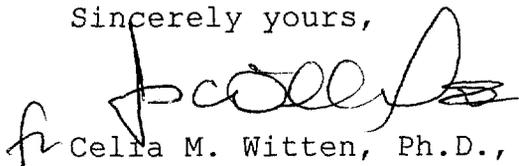
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. Mark E. Apgar

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

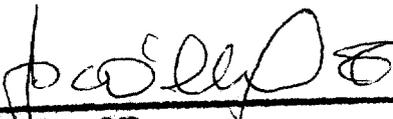
510(k) Number (if known): K961320

Device Name: Cross Medical Bone Plate System

**Indications For Use:**

The **Cross Medical Bone Plate System** is intended for non-spinal applications only in the treatment of internal fixation of pelvic fractures.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices K961320  
510(k) Number \_\_\_\_\_

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_