K072250

6. 510(k) Summary

Applicant:	Kinamed, Inc.
Address:	820 Flynn Road, Camarillo, CA 93012 USA
Contact person:	Vineet K. Sarin Ph.D. 805-384-2748 (phone), 805-384-2792 (fax)
Date prepared:	August 10, 2007
Trade name:	SuperCable™ Grip and Plate System

Substantial equivalence claimed to (see Section 9.7):

NOV 0 9 2007

a) K961267 – Pioneer, Greater Trochanter Reattachment Device
b) K972223 – Pioneer, Bone Plate with Cables
c) K982545 – Biomet, BMP Cable System
d) K000734 – Pioneer, Extended Greater Trochanter Reattachment Device
e) K001709 – Pioneer, Trochanteric Reattachment Device
f) K032559 – Synthes, Titanium Locking Screws
g) K051986 – Synthes, LCP Straight Reconstruction Plates

Device Description:

The SuperCable™ Grip and Plate System consists of trochanteric reattachment grips, cable-plates, and cortical bone screws that are intended to be used in conjunction with 1.5mm diameter SuperCable Iso-Elastic Cerclage polymer cables. The cables pass through the grips and plates and provide fixation by attaching these devices to fractured or osteotomized bone fragments. Cortical bone screws may be used in combination with the cable-plates for additional fixation as deemed necessary by the surgeon user. The system includes a range of cable grip, cable-plate, and bone screw sizes and material options, with associated manual surgical instrumentation.

Trochanteric reattachment grips are available in a minimum of four lengths and contain transverse holes for the passage of cables. A cable is passed through the transverse holes and then through its own cable locking clasp, which is part of the cable system. Locking clasps are generally positioned adjacent to the grip on the anterior or posterior surface of the proximal femur. The cable hole exit geometry is designed for optimal cable trajectory and cable contact stress when the grip is affixed to the greater trochanter. Each grip contains two proximal claws that hook into or over the proximal portion of the trochanter fragment and prevent the grip from migrating distally. Each grip also contains two smaller distal claws that penetrate the trochanter fragment distally for additional fixation and stability. The longer grips incorporate an extension to allow for transversely oriented cables around the diaphysis below the lesser trochanter to better resist trochanteric migration or rotation. These longer extensions contain slots for the insertion of compression or locked cortical bone screws into the bone. The grips are available in titanium alloy, cobalt-chromium alloy, or stainless steel alloy.

Cable-plates are available in a minimum of three lengths and contain transverse holes for the passage of cables. A cable is passed through the transverse plate holes and then through its own cable locking clasp, which is part of the cable system. Locking clasps are generally positioned adjacent to the plate. The plates also contain alternating slots for the insertion of compression or

locked cortical bone screws into the bone. By combining locking screw holes with compression slots, the plates can be used as both locking devices and fracture compression devices. The plates resemble standard plates, but have figure-of-eight shaped slots that accommodate standard or locking screws. Thus the plate can be used, depending upon the fracture situation, as a compression plate, a locked internal fixator or as a system combining both techniques. The cable hole exit geometry is designed for optimal contact stress within the cable when the plate is affixed to a long bone. The cable-plates are available in titanium alloy, cobalt-chromium alloy, or stainless steel alloy.

Bone screws are standard self-tapping cortical bone screws and are available in multiple lengths. The screws heads are available in standard compression or locked designs. The bone screws are available in titanium alloy or stainless steel. The product labeling specifies the screw and plate/grip material combinations which may be used together.

Manual instrumentation includes a grip inserter/impactor, drill guide, drill, depth gage, screwdriver, and sterilization case. All implants and instruments are supplied in a non-sterile condition.

Intended use:

The SuperCable™ Grip and Plate System is indicated for use where wire, cable, or band cerclage is used in combination with a trochanteric grip or bone plate. The SuperCable™ Grip and Plate System is intended to be used in conjunction with the SuperCable™ Iso-Elastic Cerclage System for reattachment of the greater trochanter following osteotomy or fracture, and for fixation of long bone fractures.

Summary of technological characteristics compared to predicate devices:

The SuperCable Grip and Plate System's material, design, sizing, and indications are identical or similar to the predicate devices. All devices use cables, locking clasps, grips, and bone plates for trochanteric or long bone fracture fixation. All device systems use a tensioning instrument to apply compression and affix the cable to the grip, plate, and bone. Predicate devices are available in titanium alloy, cobalt-chrome alloy, or stainless steel. Predicate systems include grips, plates, and bone screws in a variety of lengths to accommodate common fracture patterns that occur clinically.

Performance Analysis:

The SuperCable Grip and Plate System presents no new risks as compared to the predicate devices. No clinical testing is required for determination of substantial equivalence. The subject devices were found to have greater strength compared to predicate devices based on mechanical and finite element analyses as described in Section 12.11.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 9 2007

Kinamed, Inc.
% Vineet K. Sarin, Ph.D.
Chief Operating Officer
820 Flynn Road
Camarillo, CA 93012

Re: K072250
Trade/Device Name: SuperCable™ Grip and Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code(s): KTT, HWC, JDQ
Dated: August 10, 2007
Received: August 13, 2007

Dear Dr. Sarin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

8. **Indications for Use**

510(k) Number (if known): K072250

Device Name: SuperCable™ Grip and Plate System

Indications For Use:

The SuperCable™ Grip and Plate System is indicated for use where wire, cable, or band cerclage is used in combination with a trochanteric grip or bone plate. The SuperCable™ Grip and Plate System is intended to be used in conjunction with the SuperCable™ Iso-Elastic Cerclage System for reattachment of the greater trochanter following osteotomy or fracture, and for fixation of long bone fractures.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bonelli MD

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

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