K972327

AUG 1 1 1997

510(k) SUMMARY
METAGEN ACTIVELOCK™ CERCLAGE SYSTEM

June 13, 1997

ADMINISTRATIVE INFORMATION

Manufacturer Name

Metagen, LLC
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Menomonie, Wisconsin 54751

Official Contact Person

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President
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Representative/Consultant

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DEVICE NAME

Classification Name

Bone Fixation Cerclage

Trade/Proprietary Name

Metagen Activelock™ Cerclage System

Common Name

Cerclage Band System

ESTABLISHMENT REGISTRATION NUMBER

Metagen, LLC is registered with FDA under Establishment Registration Number 55922.

DEVICE CLASSIFICATION

Bone fixation cerclage systems have been classified by FDA as Class II devices, as shown in 21 CFR § 888.3010. The device is reviewed by the Orthopedic and Rehabilitation Devices Panel and the Product Code for the device is JDQ. The cerclage applicator instrument is described in this Notification in order to assist in explaining the operation of the clamping system, but it is not intended to be a subject of the submission. It is an orthopedic manual surgical instrument (Product Code HXN), classified by FDA as a Class I device and exempt from Premarket Notification, according to 21 CFR § 888.4540.

CONFORMANCE WITH PERFORMANCE STANDARDS

No performance standards have been established under Section 514. Voluntary standards with which the Metagen Activelock™ Cerclage System complies include American Society for Testing and Materials (ASTM) designation F-136 (Standard Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications) and American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) Process Control Guidelines for Gamma Radiation Sterilization (ANSI/AAMI ST32-1991).

PACKAGING/LABELING/PRODUCT INFORMATION

The Metagen Activelock™ Cerclage System bone bands and clamps will be packaged in a radiation sterilizable, disposable pouch or tray. The band/clamp assembly will be held in a support tray for easy loading onto the cerclage applicator instrument. The sterilizable pouch or tray will be packaged inside a disposable paper box. Product will be provided either non-sterile (appropriately labeled) or sterile. Sterilization will be accomplished by means of Co^{60} gamma irradiation at a dose of 25 kG (2.5 Mrad) minimum. Sterilization will be validated by the bioburden method, using American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) Process Control Guidelines for Gamma Radiation Sterilization (ANSI/AAMI ST32-1991). The sterility assurance level (SAL) that Metagen intends to meet for the sterile version of the Metagen Activelock™ Cerclage System is 10^{-6}. The device is not represented to be "pyrogen free." The cerclage applicator instrument will be packaged separately, non-sterile, in heat-sealed pouches.

INTENDED USE

The Metagen Activelock™ Cerclage System is intended for

- repair of long bone fractures due to trauma or reconstruction
- reattachment of the greater trochanter in total hip arthroplasty, surface replacement arthroplasty, or other procedures involving trochanteric osteotomy

DEVICE DESCRIPTION

Design Characteristics

The Metagen Activelock™ Cerclage System is used in the management of orthopedic trauma and total joint reconstruction to secure and stabilize segments of bone. The fundamental components of the system are a 4.5 mm wide x 250 mm long metal band, a titanium sleeve which slides onto the band, and a Nitinol clamp which secures the band. There are two metal band designs in the system; a .30 mm thick Ti 6Al-4V band, and a .5mm thick Nitinol band. Both bands in this system are secured with the same Nitinol clamp. The sleeve is a low profile titanium block with slots to accept the band and sharp tines which project into the bony surface. The Nitinol clamp component provides a positive method of securing the band. When viewed from the top the clamp is an open, rectangular block. A side view shows the through slot that accepts and ultimately secures the band. Because of the super-elastic properties of the Nitinol material, the clamp component can be physically stretched along its long axis with a cerclage applicator instrument. The cerclage applicator instrument device by design limits the elongation of the slot well within the clamp's elastic range. The clamp is in no danger of undergoing permanent (plastic) deformation.

When the slot is elongated, the band fits easily through the slot. Upon release of the stretching force, the clamp retracts toward its resting position and engages the band with sufficient force to lock the band securely in place. Mechanical testing of the assembled device comparing the band in both titanium and Nitinol to 18 and 16 gage twisted monofilament wire assemblies shows that the Activelock ™ system exceeds the strength of the twisted wire assemblies.

General Operative Technique

The system is clinically applied to fractured bone segments in the same manner as currently marketed wires or cables. The "leader" end of the band is passed around the bone segments with the aid of a blunt suture which is tied through a hole in the tip of the band. The optional titanium sleeve may be placed onto the band at this time or earlier. The tip of the band is then threaded

through the clamp after the clamp has been stretched by the cerclage applicator instrument. Tensioning of the band to cause bony reduction is achieved by securing the leader end of the band to a tensioning device which is integral with the stretcher device. Tensioning can occur only when the clamp is in the stretched position. When adequate fracture reduction and alignment are obtained, the Nitinol clamp is released, securing the band in place. Typically, several band assemblies are used to stabilize a single fracture.

Material Composition

The band of the Metagen Activelock™ Cerclage System is made from either titanium alloy (Ti-6Al-4V ELI) conforming to ASTM designation F-136 (Standard Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications), or from Nitinol (shape memory alloy). The use of titanium and titanium alloy is widespread in commercially distributed, permanently implanted medical devices and the material is widely considered to be biocompatible, even being used as a negative control in biocompatibility testing.

Nitinol is an alloy consisting of nearly equal atomic percentages of nickel and titanium. The name is derived from its major elements (Ni,Ti) and the fact that it was originally developed at the US Naval Ordnance Laboratory (NOL). This is one of several types of alloy commonly referred to as a shape memory alloy (SMA). SMAs are unique in that they can exhibit dramatically different properties than do conventional alloys or metals.

One unique property is the shape memory effect in which an SMA can be plastically deformed into a desired shape then restored to its original shape with the application of heat. Another unique property is the superelastic effect in which an SMA can be mechanically deformed to a large strain (i.e. 8%), returning to its original shape upon removal of the deforming force. Although the composition of the SMA is similar for both effects previously mentioned, the temperature ranges in which the effects occur vary. The Metagen Activelock™ Cerclage System uses the superelastic effect to provide the clamping force needed to securely lock the band in place. The temperature sensitive shape memory property of the material is not utilized.

The TiO_2 oxide layer found on Nitinol leads to its excellent biocompatibility and corrosion resistance. Polarization testing of Nitinol, stainless steel, and titanium in Hank's solution has demonstrated that the corrosion resistance of Nitinol is between that of stainless steel and titanium alloy.[1] Also, in vivo testing has demonstrated the biocompatiblity of Nitinol in animals, indicating that Nitinol is more biocompatible than stainless steel.[2,3]

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[1] Speck K, and Fraker A, "Anodic Polarization Behavior of Ti-Ni and Ti-6Al-4V in Simulated Physiological Solutions," *J Dent Res,* 59(19):1590, 1980.

[2] Castleman, IS and Motzkin, SM, "The Biocompatibility of Nitinol," *Biocompatibility of Clinical Implant Materials,* vol. 1, Williams DF (ed), CRC Press, pp129-154, 1981.

[3] Duerig, TW, et al., "Superelastic Nitinol for Medical Devices," *Medical Plastics and Biomaterials,* March/April, pp 30-43, 1997.

Nitinol has been used since the early 1980s for permanent implantable devices in Japan, Germany, China and Russia [4] The Nitinol material used in this device is the same in composition as Nitinol shape memory alloys used in numerous orthopedic, orthodontic and intravascular medical devices. Its use in commercially distributed, permanently implanted medical devices has been established in the United States since 1989, with the clearance of the Mitek Bone Anchor (K892126).[5] Nitinol is also used in the Simon Nitinol Filter (K894703), a vena cava filter designed to arrest significant thrombi on their way to the right side of the heart and lungs, while permitting the passage of normal blood. The CRI Cynosar Catheter (K904785/A) is also a Nitinol device cleared by FDA. In addition, Nitinol is used in a wide array of staples, plates, and pins used for bone fixation. Copies of references on Nitinol and its use in biological applications are shown in Exhibit V

EQUIVALENCE TO MARKETED PRODUCT

Metagen submits the following information to demonstrate that the Metagen Activelock™ Cerclage System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices or is a preamendments device: Encore Orthopedics CCG Cerclage System, DePuy Control Cable System, Howmedica Dall-Miles Stainless Steel Cable, and monofilament cerclage wire from manufacturers such as Ethicon and Zimmer.

Intended Uses

The indications for use for the Metagen Activelock™ Cerclage System and the predicate devices are substantially the same. All are intended for repair of long bone fractures due to trauma or reconstruction, reattachment of the greater trochanter in total hip arthroplasty, surface replacement arthroplasty, or other procedures involving trochanteric osteotomy.

Design and Materials

The design and functional characteristics of the Metagen Activelock™ Cerclage System and the Encore Orthopedics CCG Cerclage System (K932024) are fundamentally the same. Each is a cerclage band system that includes a slide fastener at one end that allows the band to encircle the bone and attach to itself in a belt-like manner. Each uses a manual tightening instrument to achieve reduction of a fracture and consolidation of bony fragments. The CCG Cerclage System uses a band made of commercially pure (CP) titanium, while the band of the Metagen Activelock™ Cerclage System is made from either Ti-6Al-4V alloy or Nitinol.

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[4] Fukuyo S, et al., "Shape Memory Implants," *Engineering Aspects of Shape Memory Alloys*, Duerig TW, et. al. (eds), Boston, Butterworth-Heinemann, p 170, 1990.

The Metagen Activelock™ Cerclage System is also comparable to preamendments stainless steel suture wire (16 gage and 18 gage) used for cerclage applications in that fracture reduction and bony fragment consolidation are achieved by applying tension to the device after it has been wrapped or threaded around the bone and fixing it in place while tension is maintained.

Substantial equivalence to cerclage cable systems, including the DePuy Control Cable System (K934557) and Howmedica Dall-Miles Stainless Steel Cable (K844068, K900926, K961569, K934058, K961283) is based on their use for fracture reduction and bony fragment consolidation by applying tension to the device after it has been wrapped or threaded around the bone and fixing it in place while tension is maintained, plus the similarity of clamping methods. The predicate devices use a crimp, swage or sleeve in order to maintain tension on the cable after placement and tensioning.

Mechanical Testing

In order to show equivalence of the Metagen Band/NiTi Clamp System to clinically accepted monofilament stainless steel cerclage wire under tensile load, static tensile tests were performed. Both 16 gage and 18 gage AISI Type 316L stainless steel cerclage wires were tested and were compared with both maximum material condition (MMC) and least material condition (LMC) clamps and bands of the Metagen system. Based on the test results, the data support the hypothesis that the Metagen band/NiTi clamp design provides tensile strength equal to or greater than that of clinically accepted 16 and 18 gage stainless steel cerclage wire.

SUMMARY: TABLE OF SUBSTANTIAL EQUIVALENCE

The Metagen Activelock™ Cerclage System is substantially equivalent to the Encore Orthopedics CCG Cerclage System, monofilament suture wire, DePuy Control Cable System and Howmedica Dall-Miles Stainless Steel Cable in the following respects:

	Subject Device	Predicate Devices			
	Metagen Activelock™ Cerclage System	Encore Orthopedics CCG Cerclage System (K932024)	Mono-filament suture wire (Ethicon, Zimmer, others)	DePuy Control™ Cable System (K934557)	Howmedica Dall-Miles Stainless Steel Cable (K844068, K900926, K961569, K934058, K961283)
INTENDED USE					
Repair of long bone fractures, reattachment of the greater trochanter, or other orthopedic repairs where cerclage wiring is indicated	YES	YES	YES	YES	YES
DESIGN					
Cerclage type	Band	Band	Mono-filament wire	Multi-filament cable	Multi-filament canle
Clamping method	Release of superelastic clamp	Slide fastener	Wire twist	Crimp sleeve	Crimp sleeve
MATERIALS					
Cerclage element	Ti alloy or Nitinol	CP Ti	Stainless steel	Co-Cr-W-Ni alloy	Stainless steel
Clamp	Nitinol	CP Ti	NA	Co-Cr-W-Ni alloy	Stainless steel

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Floyd G. Larson
President
Pacific Materials and Interfaces
4329 Graydon Road
San Diego, California 92130

AUG 11 1997

Re: K972327
Trade Name: Metagen Activelock™ Cerclage System
Regulatory Class: II
Product Code: JDQ
Dated: June 13, 1997
Received: June 23, 1997

Dear Mr. Larson:

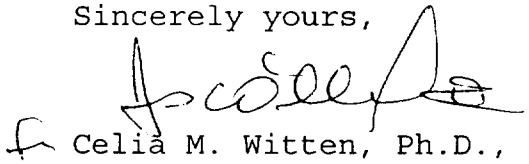
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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,



for 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

K972327

Indications for Use Statement

Device Name: Metagen Activelock™ Cerclage System

Indications for Use:

Repair of long bone fractures due to trauma or reconstruction

Reattachment of the greater trochanter in total hip arthroplasty, surface replacement arthroplasty, or other procedures involving trochanteric osteotomy

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972327