

K983976

DEC 30 1998

510(k) SUMMARY
METAGEN ACTIVELOCK™ WIRE CERCLAGE
SYSTEM

Nov 5, 1998

ADMINISTRATIVE INFORMATION

Manufacturer Name Metagen, LLC
Origen Center
428 Technology Drive East
Menomonie, Wisconsin 54751

Official Contact Person Wesley Johnson
President
Telephone (715) 232-4880
Fax (715) 235-9570

DEVICE NAME

Classification Name Bone Fixation Wire cerclage
Trade/Proprietary Name Metagen ActiveLock™ Wire Cerclage System
Common Name Wire Cerclage System

ESTABLISHMENT REGISTRATION NUMBER

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

DEVICE CLASSIFICATION

Bone fixation wire 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 wire 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™ Wire Cerclage System complies include:

ASTM F-799 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants

ANSI/AAMI ST32-1991 American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) Process Control Guidelines for Gamma Radiation Sterilization

PACKAGING/LABELING/PRODUCT INFORMATION

The Metagen ActiveLock™ Wire Cerclage System components will be packaged in a radiation sterilizable, disposable pouch or tray. The Wire/Clamp assembly will be held in a support tray for easy loading onto the wire 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 Co⁶⁰ 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™ Wire Cerclage System is 10⁻⁶. The device is not represented to be "pyrogen free." The wire cerclage applicator instrument will be packaged separately in heat-sealed pouches labeled non-sterile.

INTENDED USE

The Metagen ActiveLock™ Wire 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
- Sternotomy closure
- Sublaminar and intrafacet wiring of the spinal column

DEVICE DESCRIPTION

Design Characteristics

The Metagen ActiveLock™ Wire Cerclage System is used in the management of orthopedic trauma and total joint reconstruction to secure and stabilize segments of bone. There are two versions of the device disclosed in this submission. The fundamental components of each device are a straight, annealed CoCr alloy wire and a novel Clamp device to secure the wire. The wire is 16.5 gage (.048 inch) fully annealed CoCr alloy. (ASTM F-799). A Clamp is provided to secure the wire after tensioning. The Clamp is offered in a “Single” configuration, which secures opposing ends of a single wire, and a “Double” configuration, which secures the free ends of two adjacent wires.

General Operative Technique

The system is clinically applied to fractured bone segments in the same manner as currently marketed wires or cables. The Clamp is placed in the applicator instrument and the wire is fed through the elongated hole all the way to the stop on the wire. The opposite end of the wire is passed around the bone segments with the aid of a wire passer instrument. The wire is then threaded through the adjacent elongated hole in the Clamp and secured in the tensioning element of the applicator. Tensioning can occur only when the Clamp is in the elongated position. When adequate fracture reduction and alignment are obtained, the Clamp is released, securing the wire in place. Typically, several wire assemblies are used to stabilize a single fracture according to accepted surgical practice.

Material Composition

The wire of the Metagen ActiveLock™ Wire Cerclage System is made of CoCr alloy, which is generally available in a composition conforming to ASTM F-799, shown in Exhibit III. This material is commonly used as external fixation pins, cerclage wire for sternotomy closure and other cerclage applications where very high strength is required. The material is supplied in the fully annealed, malleable condition to optimize handling characteristics.

The Clamp is manufactured from NiTi alloy (Nitinol). 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 Ordinance Laboratory (NOL). It is one of several types of alloy commonly referred to as a shape memory alloy (SMA). SMAs are unique in that they 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™ Wire Cerclage System uses the superelastic effect to provide the Clamping force needed to securely lock the wire in place. The temperature sensitive, shape-memory property of the material is not utilized.

EQUIVALENCE TO MARKETED PRODUCT

The Metagen ActiveLock™ Wire Cerclage System is substantially equivalent in indications and design principles to the following predicate or pre-amendment devices:

- Metagen ActiveLock™ Cerclage System (K972327) featuring a bone Band device
- Monofilament wire from manufacturers such as Ethicon and Zimmer
- DePuy Control Cable System
- Howmedica Dall-Miles Stainless Steel/CoCr Cable

Intended Use

The indications for use for the Metagen ActiveLock™ Wire Cerclage System and the predicate devices are the same. All of the cable systems are intended for repair of long bone fractures due to trauma or reconstruction, reattachment of the greater trochanter in total hip arthroplasty, or other procedures involving trochanteric osteotomy. The monofilament wire and most cable systems are indicated for sternotomy closure and segmental sublaminar or intrafacet wiring of the spinal column.

Design and Materials

The design and functional characteristics of the Metagen ActiveLock™ Wire Cerclage System are fundamentally the same as the Metagen ActiveLock™ Cerclage Band system. Each system features a novel locking Clamp to secure the cerclage device. Each uses a manual tightening instrument to achieve reduction of a fracture and consolidation of bony fragments. The band of the Metagen ActiveLock™ Cerclage System is made of titanium alloy or Nitinol, while the wire of the Metagen ActiveLock™ Wire Cerclage System is made from CoCr alloy.

The Metagen ActiveLock™ Wire Cerclage System is also comparable to pre-amendment stainless steel suture wire (16 gage). Each device can be used to reduce and a fracture by applying tension, then is fixed in place. In general, monofilament wire is secured by twisting the wire on itself, whereas the subject device is secured by a novel Clamping method.

The subject device is also equivalent to cerclage cable systems, including the DePuy Control Cable System (K934557) and Howmedica Dall-Miles Stainless Steel Cable (K844068, K900926, K961569). Clamping methods for the predicate and subject devices are similar. The predicate devices use a crimp, swage or sleeve in order to maintain tension on the cable after placement and tensioning. Once the cable has been secured by a crimp it can only be removed by cutting. The subject device can be easily removed , re-tensioned and secured without compromising its strength.

Mechanical Testing

Mechanical properties of the subject device were evaluated and compared to 16 gage monofilament wire. The test methods used were identical to those used in K972327 (ActiveLock™ Cerclage Band). The data demonstrate that the Metagen wire/Clamp design provides tensile strength equal to or greater than that of clinically accepted 16 gage stainless steel wire.

SUMMARY: TABLE OF SUBSTANTIAL EQUIVALENCE

The Metagen ActiveLock™ Wire Cerclage System is substantially equivalent to the Encore Orthopedics CCG Wire 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™ Wire Cerclage System	Encore Orthopedics CCG Wire Cerclage System (K932024)	Mono-filament suture wire (Ethicon Zimmer, others)	DePuy Control™ Cable System (K934557)	Howmedica Dall-Miles Stainless Steel Cable (K844068, K900926, K961569)
INTENDED USE					
Repair of long bone fractures, reattachment of the greater trochanter, and other orthopedic repairs where cerclage wiring is indicated	YES	YES	YES	YES	YES
DESIGN					
Wire cerclage type	Wire	Wire	Wire	Multi-filament cable	Multi-filament cable
Clamping method	Release of superelastic Clamp	Slide fastener	Wire twist	Crimp sleeve	Crimp sleeve
MATERIALS					
Cerclage	CoCr alloy	CP Ti	Stainless steel	Co-Cr-W-Ni alloy	Stainless steel
Clamp	Nitinol	CP Ti	None	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

DEC 30 1998

Mr. Wesley Johnson
President
Metagen L.L.C.
Origen™ Center
428 Technology Drive East
Menomonie, Wisconsin 54751

Re: K983976
Trade Name: Metagen ActiveLock™ Wire Cerclage System
Regulatory Class: II
Product Code: JDQ
Dated: November 5, 1998
Received: November 9, 1998

Dear Mr. Johnson:

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 (Pre-market 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,



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

K983976

Indications for Use Statement

Device Name: Metagen ActiveLock™ Wire 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

Sternotomy closure

Sublaminar and intrafacet wiring of the spinal column

(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 _____

[Handwritten Signature]

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number 1213976