K980020

510(k) Summary prepared December 30, 1997

APR - 3 1998

Manufacturer Identification

Metagen, LLC
428 Technology Drive East
Menomonie, Wisconsin 54751

Official Contact Person

Wesley D. Johnson
President
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DEVICE IDENTIFICATION

Proprietary Name

ActiveLock™ Modular Femoral Hip System

Common Name

Modular Hip Replacement System.

Classification Name and Reference

Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. 21 CFR 888.3353 [HA version]

Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. 21 CFR 888.3358 [TPS version]

Proposed Regulatory Class

The Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel of FDA has recommended Class II, Performance Standards, for this device.

Device Product Codes

87 JDO - Device, Fixation, Proximal Femoral, Implant

SUBSTANTIAL EQUIVALENCE INFORMATION

The ActiveLock™ Modular Femoral Hip System demonstrates substantial equivalence, relative to the intended use, materials and design, to several pre-amendment and post-amendment

devices, including implants marketed by Biomet (Impact, K942027; Mallory-Head Modular Porous Series, K921181), Joint Medical Products Corporation/Johnson & Johnson (S-ROM, K851422, K912713, K913231), Wright Medical Technology (Infinity, K942115), and Smith & Nephew Richards (RMHS, K912593).

DEVICE DESCRIPTION

Intended Use

The ActiveLock™ Modular Femoral Hip System is intended for primary or revision reconstruction, with or without bone cement, of the femoral portion of severely disabled and/or very painful hip joint, where radiographic evidence of sufficient sound bone is present.

Design

The ActiveLock™ Modular Femoral Hip System is a matrix of interchangeable components (STEM, BODY, ACTUATOR, FEMORAL HEAD) that can be locked together to form a single femoral hip prosthesis. A description of the components is given below.

Stem

The **Stem** component is cylindrical, straight, and fluted with a slot in the coronal plane that extends along the distal third of its length. The proximal aspect of the Stem is a smooth tubular cylinder designed to mate with the Body component. The Stem component is manufactured from wrought Ti 6Al-4V alloy and is offered in a variety of lengths, straight or curved, to accommodate primary and revision surgery.

Body

The **Body** component is wedge-shaped and symmetrical in the coronal plane. Design variations of the Body include primary, revision, and calcar replacement components. All Body designs incorporate identical cylindrical bores for modular attachment to the Stem and the same modified Morse taper for attachment of Metagen Femoral Heads. All Body designs are available with either porous CpTi plasma spray or plasma-sprayed smooth HA (hydroxyapatite) coating. The Body component is manufactured from wrought Ti 6Al-4V alloy. When attached to the Stem component, the Body component provides fixation to the proximal metaphyseal region of the femur.

Actuator

The **Actuator** is manufactured of Nickel-Titanium alloy (NiTi). It is a cylindrical, tubular locking component.

Femoral Head

The Femoral Head is a CoCr alloy articulating component with a modified female Morse taper. The components are spherically ground and polished to 22 mm, 26 mm, 28 mm, and 32 mm diameters, and are available in four offsets –5 mm, 0 mm, +5 mm, and +10 mm.

Components are matched according to four distinct "**FAMILY**" designations. The four families are the "A" family, "B" family, "C" family, and the "D" family. The "A" family corresponds to the smallest sizes, the "B" and "C" family to the mid-range sizes, and the "D" family to the largest sizes. The Stem and Body components are only interchangeable within their respective families, and can only be locked by the Actuator in that family.

Composition/Materials

The ActiveLock™ Modular Femoral Hip System is composed of titanium alloy (Ti-6Al-4V ELI) conforming to ASTM Specification F136. The Femoral Head is made from wrought Co-Cr-Mo alloy conforming to ASTM Specification F1537.

The Actuator of the ActiveLock™ Modular Femoral Hip System is made from NiTi alloy, a nickel-titanium shape memory alloy. NiTi alloy is currently being used in a number of implant devices and has a long clinical history as an implant material. In addition, NiTi alloy is being used in orthopedic applications for bone anchors.

Mechanical Characterization

The ActiveLock™ Modular Hip System has been evaluated by use of the static and fatigue tests. It has been shown to be substantially equivalent to the predicate devices.

Corrosion Testing

The components and materials of the ActiveLock™ Modular Hip System have been tested in corrosion. It has been shown that the materials of the system are resistant to corrosion.

Summary: Table of Substantial Equivalence

	Subject Device	*Predicate Devices*				
MANUFACTURER	Metagen	Biomet		Joint Medical/ J&J	Wright Medical Technology	S&N Richards
SYSTEM NAME	Modular Femoral Hip System	Impact (K942027)	Mallory-Head (K921181)	S-ROM (K851422, K912713, K913231)	Infinity (K942115)	Modular Hip System (RMHS) (K912593)
DESIGN FEATURES						
Cementless fixation	YES	YES	YES	YES	YES	YES
Modular proximal body/stem	YES	YES	YES	YES	YES	YES
Straight cylindrical distal stem	YES			YES	YES	YES
Flexible distal stem	YES	YES	YES	YES	YES	
Maximized projected area	YES	YES	YES	YES	YES	YES
Collarless	YES	YES	YES	YES		YES
Modular head with modified Morse taper	YES	YES	YES	YES	YES	YES
MATERIALS						
Ti-6Al-4V	YES	YES	YES	YES	YES	YES
NiTi alloy Actuator	YES					
HA on proximal surfaces	YES			YES		
TPS on proximal surfaces	YES	YES	YES	YES	YES	
Co-Cr-Mo Modular Head	YES	YES	YES	YES	YES	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 1998

Mr. Wesley D. Johnson
President
Metagen, LLC
428 Technology Drive East
Menomonie, Wisconsin 54751

Re: K980020
ActiveLock™ Modular Hip System
Regulatory Class: II
Product Codes: MEH, LPH, and JDI
Dated: December 30, 1997
Received: January 5, 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). This decision is based on consideration of the specific design of stem and coating composition detailed in this application. You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation:

> You may not label or in any way promote the HA coated versions of these devices for "biological attachment, enhanced clinical or radiographic performance, enhanced fixation and/or long-term stable fixation." The data presented support equivalence with no additional claims over a conventional press-fit hip prosthesis (i.e., mechanical interlock, only).

Additional limitations for more specific claims of safety and effectiveness may be forthcoming. Should additional limitations be applied you will be contacted in writing to inform you of the additional labeling limitations.

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.

You may market your device under the above limitations as class II devices. These devices would be considered not substantially equivalent to a legally marketed predicate device if labeled with other intended uses and/or claims of safety or effectiveness. Any other intended uses or claims may cause the device to be classified into Class III under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing.

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. 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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

Device Name: ACTIVELOCK™ MODULAR FEMORAL HIP SYSTEM

The ActiveLock™ Modular Femoral Hip System is intended for primary or revision reconstruction, with or without bone cement, of the femoral portion of severely disabled and/or very painful hip joint, where radiographic evidence of sufficient sound bone is present.
Clinical Indications for Use are:

1. noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. rheumatoid arthritis;
3. correction of functional deformity;
4. revision procedures where other treatments or devices have failed; and,
5. treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980020

Prescription Use X OR Over-The-Counter Use_____