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510(k) Summary (K980609) Segmental Defect Replacement System

510(k) Summary prepared February 12, 1998

MANUFACTURER IDENTIFICATION

Metagen, LLC
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Menomonie, Wisconsin 54751

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DEVICE IDENTIFICATION

Proprietary Name
Segmental Defect Replacement System

Common Name
Segmental Defect Prosthesis

Classification Name and Reference
Rod, Fixation, Intramedullary and Accessories, 21CFR 888.3020

Regulatory Classification
The Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee of FDA has recommended Class II, Performance Standards, for this device.

Device Product Codes
Product Code 87HSB has been assigned to this device.

DEVICE DESCRIPTION

Intended Use
The Segmental Defect Replacement System, when used with bone cement, is intended for reconstruction of the humeral diaphysis with an extensive destructive bone lesion due to metastatic disease, myeloma, or lymphoma, that places the humerus at risk for pathologic fracture.

Design
The Segmental Defect Replacement System is an array of proximal and distal intramedullary rods which, when locked together, replace the resected diseased segment and provide internal fixation in the remaining humeral bone stock. The system includes a locking device to secure the rod components, and instrumentation to facilitate insertion.

Mechanical Characterization
The Segmental Defect Replacement System has been evaluated by use of the static and fatigue tests. It has been shown to be substantially equivalent to the predicate devices.

SUMMARY: TABLE OF SUBSTANTIAL EQUIVALENCE

The Segmental Defect Replacement System is substantially equivalent to the following predicate devices:

Subject Device	Predicate Devices		Related Devices		
Segmental Defect Replacement System	EZ-Fix Midshaft Humeral Intramedullary Rod System. Biodynamics Technologies, Inc. (K962553)	Howmedica Modular Proximal Humerus Replacement System. Howmedica (K954559)	Modular Oncology System Technology. Intermedics Orthopedics, Inc. (Sulzer Orthopedics) (K960626)	SOS Proximal Femur. Wright Medical Technology (K933281)	Modular Intercalary Humeral Spacer. Mayo Clinic
Intended Use					
Reconstruction of the humeral diaphysis with an extensive destructive bone lesion due to metastatic disease, myeloma, or lymphoma, that places the humerus at risk for pathologic fracture	Midshaft fractures of the humerus	Replacements of the proximal humerus secondary too extensive bone loss or bone disease. Bone loss can be due to tumor resection, revision arthroplasty or trauma.	Replacement of the proximal, distal or total femur where the amount of femoral resection and restoration is extreme (e.g., in oncology cases).	Procedures in which a variable resection length prosthesis is necessary to accommodate the condition of the femur, e.g., severe bone loss in hip arthroplasty for osteosarcoma or fractured femur or revision arthroplasty.	Pathological fracture, impending pathological fracture or failure of attempted internal fixation techniques secondary to segmental destructive bone lesions of the humeral diaphysis in disseminated malignancies
Design					
Modular bistemmed intramedullary rod system with rigid cam locking mechanism designed to provide intraoperative adjustment after cementing components into the proximal and distal segments of the resected humerus.	Intramedullary rod system with screw holes, to be used without bone cement	Modular humeral replacement system, consisting of head, body and stem segments. Cemented.	Modular hip and knee system consisting of a proximal femoral replacement, intramedullary stems and femoral segments, a distal femoral replacement which mates with a tibial component, and a patella.	Modular hip system consisting or a femoral neck component, an optional mid-section component and a stem component with Morse taper connections. Cemented.	Modular bistemmed intramedullary rod system with conical coupling mechanism locked with set screws designed to provide intraoperative adjustment after cementing components into the proximal and distal segments of the resected humerus.
Materials					
Ti-6Al-4V NiTi alloy (locking system)	Ti-6Al-4V	Co-Cr-Mo alloy (head and stem) Ti alloy (body)	Ti-6Al-4V UHMWPE (patella)	Ti-6Al-4V	Ti-6Al-4V

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 1998

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

Re: K980609
Trade Name: Segmental Defect Replacement System
Regulatory Class: II
Product Code: HSB
Dated: February 17, 1998
Received: February 17, 1998

Dear Mr. Johnson:

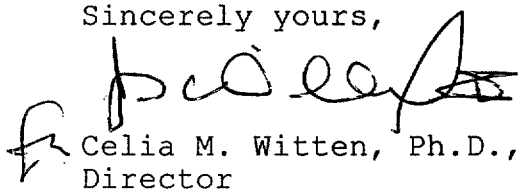
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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: SEGMENTAL DEFECT REPLACEMENT SYSTEM, K980609

The Segmental Defect Replacement System, when used with bone cement, is intended for reconstruction of the humeral diaphysis with an extensive destructive bone lesion due to metastatic disease, myeloma, or lymphoma, that places the humerus at risk for pathologic fracture.

The Clinical Indication for Use is:

"The Segmental Defect Replacement System, when used with bone cement, is indicated for pathologic fractures or impending pathologic fractures of the diaphysis of the humerus secondary to metastatic bone disease and hematologic malignancies."

(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 K980609