K062693

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

SEP 2 9 2006

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the GLADIATOR™ Bipolar System.

Submitted By:	Wright Medical Technology, Inc.
Date:	September 8, 2006
Contact Person:	Matt Paul Regulatory Affairs Specialist
Proprietary Name:	GLADIATOR™ Bipolar System
Common Name:	Bipolar Hip System
Classification Name and Reference:	21 CFR 888.3390 Prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented - Class II
Device Product Code and Panel Code:	Orthopedics/87/KWY

DEVICE INFORMATION

A. Intended Use

The **GLADIATOR™ Bipolar System** is indicated for the following conditions:

1) pathological fractures of the femoral neck
2) non-union of femoral neck fractures
3) aseptic necrosis of the femoral head and neck
4) primary pathology in the young involving the femoral head but with a non-deformed acetabulum.

B. Device Description

The design features of the GLADIATOR™ Bipolar System are summarized below:

- Shells manufactured from cast CoCr alloy
- Shells available in O.D. sizes 36-65mm
- Bearing insert manufactured from cross-linked UHMWPE
- Bearing insert available in I.D. (femoral head) sizes 22, 28, 32, 36mm
- Locking and support rings manufactured from UHMWPE
- All components permanently assembled during production

C. Substantial Equivalence Information

The indications for use of the GLADIATOR™ Bipolar System are identical to the previously cleared predicate device. The design features and materials of the subject device are substantially equivalent to those of the respective predicate devices. The fundamental scientific technology of the modified device has not changed relative to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 2006

Wright Medical Technology, Inc.
% Mr. Matt Paul
Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

Re: K062693
Trade/Device Name: GLADIATOR™ Bipolar System
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWY
Dated: September 8, 2006
Received: September 11, 2006

Dear Mr. Paul:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its 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

Indications for Use

510(k) Number (if known):

Device Name: GLADIATOR™ Bipolar System

Indications For Use:
The GLADIATOR™ Bipolar System is indicated for the following conditions:
1) pathological fractures of the femoral neck
2) non-union of femoral neck fractures
3) aseptic necrosis of the femoral head and neck
4) primary pathology in the young involving the femoral head but with a non-deformed acetabulum.

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)

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

510(k) Number K062643