SEP 2 9 2005

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K043099

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510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

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 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the LINEAGE® HA Acetabular Shell.

Submitted By:	Wright Medical Technology, Inc.
Date:	November 06, 2004
Contact Person:	Jeanine H. Redden Regulatory Affairs Specialist II
Proprietary Name:	LINEAGE® HA Acetabular Shells
Common Name:	Acetabular Shells
Classification Name and Reference:	Prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calicum-phosphate- Class II 21 CFR 888.3358 Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented- Class II 21 CFR 888.3330 Hip joint metal/ metal semi-constrained, with an uncemented acetabular component prosthesis – Class III
Device Product Code and Panel Code:	Orthopedics/87/MEH/LPH/KWA

DEVICE INFORMATION

A. INTENDED USE

The LINEAGE® HA Acetabular Shells are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed
5. treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The LINEAGE® HA Acetabular Shells are single use components, intended for use as part of an uncemented total hip arthroplasty system; in conjunction with WMT's poly or metal liners; and ceramic or metal femoral heads.

B. DEVICE DESCRIPTION

A Hydroxylapatite (HA) coating is being added to the LINEAGE® Acetabular Shells previously cleared for market in the US.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The LINEAGEE® HA Acetabular Shells are substantially equivalent to the predicate devices previously cleared for market. The safety and effectiveness of the LINEAGE® HA Acetabular Shells is adequately supported by the substantial equivalent information, materials data, and testing results provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 9 2005

Ms. Jeanine H. Redden
Senior Regulatory Affairs Specialist
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K043099
Trade/Device Name: LINEAGE® HA Acetabular Shells
Regulation Numbers: 21 CFR 888.3330
Regulation Names: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Codes: KWA, LPH, MEH
Dated: August 15, 2005
Received: August 26, 2005

Dear Ms. Redden:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

WRIGHT.
TM

Indications for Use

510(k) Number (if known): K043099

Device Name: LINEAGE® HA Acetabular Shells

Indications For Use:

The LINEAGE® HA Acetabular Shells are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
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3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed
5. treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The LINEAGE® HA Acetabular Shells are intended for single patient use only.

Mark A. Milliren

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

510(k) Number K043099

Prescription Use __X____ AND/OR Over-The-Counter Use __No__
(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)

headquarters
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