AUG 31 2000

K002149

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

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™ Acetabular System.

Submitted By:	Wright Medical Technology, Inc.
Date:	July 11, 2000
Contact Person:	Ehab M. Esmail Senior Regulatory Affairs Associate
Proprietary Name:	LINEAGE™ Acetabular System
Common Name:	Metal/ Polymer Acetabular Components
Classification Name and Reference:	21 CFR 888.3358 Prosthesis, Hip, Semi-Constrained, metal/polymer, Uncemented – Class II
Device Product Code and Panel Code:	Orthopedics/87/LPH

DEVICE INFORMATION

A. INTENDED USE

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;
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 that are unmanageable using other techniques.

The LINEAGE™ Acetabular System are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of an uncemented total hip arthroplasty.

B. DEVICE DESCRIPTION

The LINEAGE™ Acetabular System consists of metal acetabular shells and UHMWPE acetabular liners.

The LINEAGE™ Acetabular Shell will be available in a hemispherical titanium alloy shell with and without a 14° peripheral rim flare. The shells will be coated with commercially pure titanium plasma spray or porous beads.

Design features of the LINEAGE™ Acetabular Shell are summarized below:

- Total hemispherical design
- Hemispherical design with 14° flare
- Coated with CP Ti plasma spray or porous beads
- Solid, quadrant, and multi-hole options
- Threaded apical hole plug

The LINEAGE™ Acetabular Liners will be available with a 0° and 15° overhangs with/without a 4+mm lateralized shift. The Liner's internal geometry will be intended to be used with our existing femoral heads manufactured from cobalt chrome or ceramic with WMT12/14 taper, Orthomet® taper and A-line taper. The LINEAGE™ Liner's external geometry will be designed to accept the LINEAGE™ Acetabular Shells.

Design features of the LINEAGE™ Acetabular Liner are summarized below:

- 360° liner overhang positioning options
- Features an 18° male taper and peripheral ring assembly to lock the liner into the acetabular shell
- The lip of the 15° liner will be machined to 210°
- The inserts will be offered with 0°and 15° overhangs
- The inserts will also be offered with a 4+mm lateralized shift
- Internal diameter will have a 2mm chamfer to minimize impingement.

The thinnest part of any UHMWPE articulating insert will be greater than 4 mm if attached to a metal or ceramic backing.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material, type of interface, and design features of the LINEAGE™ Acetabular System are substantially equivalent to the competitive devices previously cleared for market. The safety and effectiveness of the LINEAGE™ Acetabular System are adequately supported by the substantial equivalence information, materials data, and testing results provided within the Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2000

Mr. Ehab M. Esmail
Senior Regulatory Affairs Associate
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K002149
Trade Name: Lineage™ Acetabular System
Regulatory Class: II
Product Code: LPH
Dated: July 13, 2000
Received: July 17, 2000

Dear Mr. Esmail:

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 control provisions of the Act. The general control 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 at (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, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002149

Device Name: LINEAGE™ Acetabular System

Indications For Use:

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:

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5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dianne R. Vachner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002149

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No