K004043

JUL 1 3 2001

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 Metal TRANSCEND® Articulation System.

Submitted By:	Wright Medical Technology, Inc.
Date:	December 28, 2000
Contact Person:	Ehab M. Esmail Senior Regulatory Affairs Associate
Proprietary Name:	**Metal TRANSCEND®** **Articulation System**
Common Name:	TOTAL HIP SYSTEM
Classification Name and Reference:	21 CFR 888.3320 Hip joint metal/ metal semi-constrained, with a cemented acetabular component prosthesis – Class III 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/KWA, JDL

DEVICE INFORMATION

A. INTENDED USES/ INDICATIONS

The Metal TRANSCEND® Articulation System is 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

The Metal TRANSCEND® Articulation System components are for single use only.

B. DEVICE DESCRIPTION

The Metal TRANSCEND® Articulation System consists of components that are identical to the previously submitted components under the Metal TRANSCEND® Articulation System IDE: metal acetabular shells, metal acetabular liners, and metal femoral heads.

Design features of the Metal TRANSCEND® Acetabular Shell are summarized below:

- Manufactured from Ti6Al4V conforming to ASTM F-136 or ASTM F620
- Porous coated with commercially pure titanium (ASTM F67 or F 1580) sintered beads
- Features three screw holes and an apical hole
- Designed for use with Apical Hole Plug and bone screws
- Internal geometry of the shell features an 18.8750° (included) taper to accept acetabular liners
- Available in 12 sizes ranging from 46mm to 68mm in 2mm increments

Design features of the Metal TRANSCEND® Acetabular Liner are summarized below:

- Manufactured from cast cobalt-chromium-molybdenum conforming to ASTM F75
- Designed for use with metal acetabular shell
- Available in three inside diameters: 28mm, 32mm, and 36mm

Design features of the Metal TRANSCEND® Femoral Head are summarized below:

- Manufactured from cast cobalt-chromium-molybdenum conforming to ASTM F75
- Available in three sizes: 28mm, 32mm, and 36mm
- Available in four neck lengths: short, medium, long, and extra-long

C. MATERIALS

The materials used for the Metal TRANSCEND® Articulation System are substantially equivalent to competitive devices previously cleared for market and identical to the previously submitted components under the Metal TRANSCEND® Articulation System IDE.

Acetabular Shells

- Titanium Alloy, Ti6Al4V, wrought or forged (ASTM F-136, ASTM F-620)

- Porous coated over the entire exterior surface (ASTM F-67 or F 1580)

Acetabular Liners

- Cast Cobalt-Chromium-Molybdenum CoCrMo (ASTM F75)

Femoral Head

- Cast Cobalt-Chromium-Molybdenum CoCrMo (ASTM F75)

D. CLINICAL DATA

The Metal TRANSCEND® Articulation System was previously submitted under the Metal TRANSCEND® Articulation System IDE. Under the IDE, clinical data was collected prospectively from multi-sites

After excluding a single site with significantly poorer survival than all other sites that was identified as having problems with surgical technique, 2-year cumulative survival was found to be clinically equivalent to (no worse than) the Dobbs metal on metal cohort. Nearly 90% of procedures resulted in "at least good results" at 1 and 2 years as determined by the Harris Hip Score, results that compared favorably with literature-based cohorts of THR. There was more than a 50% increase in the SF-12 physical function component score. Complications and adverse events were rare. Radiolucencies >2mm were rare. There were no findings of subsidence of the stem or migration of the cup >2mm.

In conclusion, this controlled clinical trial provides substantial evidence that the Metal TRANSCEND™ Articulation System is as safe and effective as approved predicate devices with clinically equivalent patient outcomes relative to such devices, thus supporting a 510(k) claim.

E. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material, type of interface, and design features of the Metal TRANSCEND® Articulation System are substantially equivalent to the competitive devices. The safety and effectiveness of the Metal TRANSCEND® Articulation System are adequately supported by the substantial equivalence information, materials data, testing results, and clinical data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 3 2001

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

Re: K004043
Trade Name: Metal TRANSCEND Articulation System
Regulation Number: 21 CFR 888.3320, 21 CFR 888.3330
Regulatory Class: III
Product Code: JDL, KWA
Dated: April 16, 2001
Received: April 17, 2001

Dear Mr. Esmail:

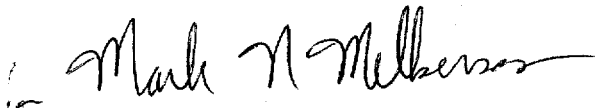
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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

Metal TRANSCEND® Articulation System

INDICATIONS STATEMENT

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.

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K004043