JUL 1 2002 K021349

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:	April 26, 2002
Contact Person:	Ehab M. Esmail Manager Regulatory Affairs
Proprietary Name:	**Metal TRANSCEND®** **Articulation System (LARGER SIZES)**
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

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 previously submitted and cleared Metal TRANSCEND® Articulation System (Exhibit 1: 510(k) K004043) is composed of two pieces, a metal shell and a metal liner that mates to the shell by the use of a taper locking mechanism. This two piece design limits the size of the femoral heads. The use of a monoblock superfinished shell allows larger head sizes to be used. The new Metal TRANSCEND® Articulation System (larger sizes) should increase the range of motion and decrease the risk of dislocation as compared to the current TRANSCEND® (510(k) K004043) Metal on Metal bearing couple.

The Metal TRANSCEND® Articulation System (larger sizes) consists of the following components that are substantially equivalent to the previously cleared components submitted under the Metal TRANSCEND® Articulation System (510(k): K004043): metal monoblock acetabular shells, and metal femoral heads.

Design features of the Metal TRANSCEND® Articulation Monoblock Shell (larger sizes) are summarized below:

- Manufactured from cast cobalt-chromium-molybdenum conforming to ASTM F75
- Porous coated with CoCrMo (ASTM F75) Sintered beads
- Available sizes: ranging from 46mm to 64mm (outer diameter) in 2mm increments (The inner diameter of each shell is 10mm smaller than the outer diameter)
- The articulating surface of the implants will be superfinished (1 microinch Ra maximum) to insure form tolerance and a fine surface finish
- A one-piece acetabular shell allows the surgeon to reconstruct the acetabulum while removing very little bone to accommodate a larger Femoral Head.

Design features of the Metal TRANSCEND® Femoral Head (larger sizes) are summarized below:

- Manufactured from cast cobalt-chromium-molybdenum conforming to ASTM F75
- Available sizes: 38mm, 40mm, 42mm, 44mm, 46mm, 48mm, 50mm, 52mm, 54mm
- Available neck lengths: -3.5, 0, +3.5
- The articulating surface of the implants will be superfinished (1 microinch Ra maximum) to insure form tolerance and a fine surface finish
- The taper connection for the Metal TRANSCEND® Femoral Heads (larger sizes) will be identical to the Metal TRANSCEND® Femoral Heads (510(k):K004043) and is intended to be used with our existing femoral stems manufactured with WMT12/14 taper.

C. MATERIALS

The materials used for the Metal TRANSCEND® Articulation System (larger sizes) are substantially equivalent to competitive devices previously cleared for market.

Monoblock Acetabular Shells

- Cast Cobalt-Chromium-Molybdenum CoCrMo (ASTM F75)
- Porous coated with CoCrMo (ASTM F75) Sintered beads

Femoral Head

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

D. CLINICAL DATA

The intended use, material, design features, type of interface, and reported ware rates of the Metal TRANSCEND® Articulation System (larger heads) are substantially equivalent to the previously submitted and cleared Metal TRANSCEND® Articulation System (510(k): K004043).

Therefore, Clinical success similar to that of the previously cleared components submitted under the Metal TRANSCEND® Articulation System (510(k) K004043) is expected. The clinical data (TRANSCEND® Metal Articulation System Controlled Clinical Trial in support of 510(k) Statistical Analysis Report Version 8.0 December 23, 2000– Volume 1 & 2) was previously submitted under the Metal TRANSCEND® Articulation System (510(k) K004043). The 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 (larger sizes) 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 2002

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

Re: K021349
Trade Name: Metal TRANSCEND® Articular System (Larger Sizes)
Regulation Number: 21 CRF 888.3320 and 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis; and
Hip joint metal/ metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA
Dated: April 26, 2002
Received: April 29, 2002

Dear Mr. Esmail:

We have reviewed your Section 510(k) premarket 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) 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for 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

K021349

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.

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

510(k) Number K021349