Summary of Safety and Effectiveness Data

I. GENERAL INFORMATION

Device Generic Name: Total Hip System, Ceramic Articulation

Device Trade Name: Ceramic TRANSCEND® Hip Articulation System

Applicant's Name and Address: Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002

Premarket Approval (PMA) Number: P010001

Date of Panel Recommendation: None

Date of Notice of Approval to the Applicant: February 3, 2003

II. INDICATIONS FOR USE

The Ceramic TRANSCEND® Hip Articulation System is indicated for use in primary total hip arthroplasty in skeletally mature patients with non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, congenital hip dysplasia, and traumatic arthritis.

III. CONTRAINDICATIONS

- overt or latent infection in or around the hip joint;
- skeletally immature patients; and
- cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock (tight fixation is critical, bone stock must be adequate), poor skin coverage around hip joint which would create an unjustifiable risk.

IV. WARNINGS and PRECAUTIONS

WARNINGS:

- Seat the acetabular shell at a 45° inclination with 15° anteversion for proper positioning to decrease the chance for dislocation.
- Always ensure proper alignment and seating of TRANSCEND® Acetabular liner before impacting to prevent chipping or damage.
- Do not reassemble and disassemble the liner component to the acetabular shell because the locking joint and taper joint might become damaged.
- Do not scratch modular shells and tapers to prevent damage to the locking joint.
- Do not use other manufacturer's components with any of the TRANSCEND® components to prevent a mismatch of the tapers. Use only compatible Wright Medical components with the TRANSCEND® components (see product literature for list of appropriate components).
- Replace any component that has been chipped, scratched, or otherwise damaged during the implant procedure.

- Do not implant in obese patients because loading on the ceramic femoral heads may lead to fracture or loss of fixation.
- Implants are for single use only. Do not reuse an implant in order to ensure there has been no damage to the implants.
- Do not re-sterilize components and return all packages with flaws to the manufacturer.

PRECAUTIONS:

- Surgeons must review the training video and materials prior to implanting the Ceramic TRANSCEND® Hip Articulation System.
- Clean surgical debris from the interior of the shell prior to seating the liner into the shell to prevent accelerated bearing wear. Accelerated bearing wear may lead to early failure of the device.
- Use caution when handling ceramic components during assembly because of the brittle nature of ceramic material.
- Clean and dry surfaces which lock to ensure proper seating and assembly.
- Do not contour or bend an implant because it may reduce its fatigue strength and cause failure under load.
- Do not use a metal or zirconia head with the TRANSCEND® Acetabular Liner because this may accelerate bearing wear and lead to early failure of the device.
- Ensure appropriate selection of bone screw length and location to avoid damage to underlying soft tissue structures. Perforation of the pelvic wall with screws that are too long can result in internal bleeding and possible damage to vital organs.
- Avoid detachment of porous or HA coatings which could lead to increased debris particles.
- Ensure that the outer diameter of the femoral head matches the inner diameter of the acetabular liner.
- Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.
- In order to prevent sepsis, the physician is advised to follow the following recommendations:
  - Consistent use of prophylactic antibiotics.
  - Utilizing a laminar flow clean air system.
  - Having all operating room personnel, including observers, properly attired.
  - Protecting instruments from airborne contamination.
  - Impermeable draping.
- Safety and Effectiveness has not been established in patients with the following conditions:
  - revision hip arthroplasty
  - inflammatory hip joint disease
  - neuropathic hip joint disease

V. DEVICE DESCRIPTION

The Ceramic TRANSCEND® Hip Articulation System consists of ceramic on ceramic acetabular bearing couple. The bearing surfaces consist of SLT Ceramic Femoral Heads (28mm, 32mm, and 36mm) and Ceramic TRANSCEND® Acetabular Liner (28mm,

32mm, and 36mm). Both components are manufactured out of Aluminum Oxide manufactured by CeramTec.

Other components included in the TRANSCEND® Articulation System are the metal Quadrant Acetabular Shell. The acetabular shell is manufactured out of Titanium alloy (Ti-6Al-4V). It is coated with commercially pure titanium sintered beads. The acetabular shell is available in 14 sizes ranging from 46 to 72 mm in 2mm increments.

The components of the TRANSCEND® Articulation System will be implanted with commercially available Wright Medical Technology (WMT) femoral stems, apical hole bone plugs, and self-tapping cancellous bone screws.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Depending on individual circumstances, alternative procedures may include the use of other commercially available total hip replacement implants, non-surgical treatment such as reduced activity and/or pain medication; or other surgical treatments that do not involve the use of an implant, such as hip joint fusion.

VII. MARKETING HISTORY

Internationally, approximately 4270 Ceramic TRANSCEND® shells, liners, and heads have been sold since 1997. The device has not been removed from any market due to any reason related to the safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

(please refer to the Adverse Events Table 3, on page 10, for adverse events related to this study)

Potential Complications Associated with Any Total Hip Arthroplasty

1. Excessive wear of the ceramic components secondary to damage of mating wear surfaces or debris particles.
2. Although rare, metal sensitivity reactions in patients following joint replacement have been reported.
3. Implantation of foreign material in tissues can result in histological reactions involving macrophages and fibroblasts.
4. Possible detachment of the porous or HA coating which could lead to increased debris particles.
5. pain;
6. femoral or acetabular perforation, or bone fracture while seating the device;
7. damage to blood vessels resulting in hematoma;
8. temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
9. undesirable shortening or lengthening of the limb;
10. traumatic arthrosis of the hip from intraoperative positioning of the extremity;
11. cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
12. temporary or permanent neuropathies;
13. delayed wound healing;

14. infection;
15. migration, loosening, subluxation, or dislocation of the prosthesis;
16. periarticular calcification or ossification, with or without impediment to joint mobility;
17. inadequate range of motion due to improper selection or positioning of components, by femoral impingement, and periarticular calcification; and
18. death.

Potential Complications Associated with the Ceramic TRANSCEND® System

1. Wear of the alumina ceramic articulating surfaces of acetabular components has been reported following total hip replacement. Higher rates of wear may be initiated by particles of cement, metal, or other debris that can cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis, and lead to early revision surgery to replace the worn prosthetic components.
2. While rare, fatigue fracture of the prosthetic component can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.
3. Component dissociation
4. Breakage of the femoral head or acetabular insert

IX. SUMMARY OF PRECLINICAL STUDIES

A battery of pre-clinical tests was conducted on the alumina ceramic material used to make the ceramic components. The ceramic material has been well characterized and used successfully throughout the orthopaedic industry for many years. It conforms to the ASTM F603 and ISO 6474 requirements and has proven to be safe and effective.

Several nonclinical laboratory studies were conducted by Wright Medical in support of the design of the Ceramic-on-Ceramic TRANSCEND® Articulation System.

Pre-fatigue and Post-fatigue Push-Out and Lever-Out Testing on Ceramic on Ceramic

The purpose of this test was to evaluate the integrity of the insert/shell taper connection of the acetabular system. The 46mm assembly was determined to be the worst case for all the testing because it has the least amount of taper surface contact. Fatigue of the assemblies was accomplished through a gait profile or 2000 cycles. The gait profile included peak compression loading of about 2.5 times body weight (1780 Newtons), rotation of approximately ± 5°, and flexion from 0° to 30°. This profile was derived from the work presented by Komistek et al., entitled "Mathematical Model of the Human Lower Extremity"[1].

The mean push out force of TRANSCEND® group ceramic insert was determined to be 10,998 N. The test was repeated with another group of components after they had undergone 2000 cycles of physiological load. The mean push out value for that group

[1] Komistek, R. D., and et al. Mathematical Model of the Human Lower Extremity. *13th Annual Southern Biomedical Engineering Conference*.

was 13,633 N. The highest push out value reported by Tradonsky[2], et al., was 2,949 N for a "contemporary" two piece acetabular system with polyethylene liner. Compared to Tradonsky test, the TRANSCEND® has much higher shell/liner interlock. In addition, the interlock is enhanced after cyclic loading.

The lever out forces present in the hip joint can reach substantial values during extreme flexion or extension or in situations of variable head coverage. In vivo, the kinematics of these disassociation's are assumed to be a rotation of the liner about some point on the lip of the shell. The mean lever out value for TRANSCEND® was reported at 337.5 N-in and the failure was in fixturing. The ceramic inserts did not lever out of the shell, and the only failure was the lever arm breaking or the cup breaking at the lever arm. In conclusion, the pre-fatigue lever-out values demonstrated by the ceramic insert in this test exceed the maximum non-fatigue values reported by Tradonsky et al., by factors of 3.7.

Ceramic on Ceramic Torsional Test

The purpose of the test was to determine the torsional force required to dissociate the taper-fit between a ceramic insert and an acetabular shell. The 46mm assembly was determined to be the worst case for all the testing because it has the smallest amount of taper surface contact area within the implant system under consideration.

Torque values of 2.4 N-in were reported between the head and the liner. A maximum torque value of 3.22 N-in was calculated as the worst case (no lubrication). Torsional values for TRANSCEND® ceramic insert were measured after static assembly and after cyclic fatigue, and were found to be 121.8 N-in and 150.8 N-in, respectively.

The static and post-fatigue torsional resistance (Mmax)demonstrated by the assembled ceramic inserts and shell are respectively 37.8 and 46.8 times greater than the maximum torque expected *in vivo* in an artificial joint consisting of a proper pairing of ceramic cups and ball whereby

$$\boxed{Mmax - Fn * m * r}$$

Fn = Normal Component of Contact Force (2,300N ≅ 3 * Body Weight)[3]
m = Frictional coefficient 0.10 acc.
r = Lever arm relating to ball diameter/2 = 28mm/w = 14mm
Mmax = 2300N * 0.10 * 0.014m
Mmax = 3.22Nm***

***This calculation represents the worst case since the effect of lubrication (synovial or other biologic fluid) was neglected and the entire contact area was assumed to be at a radius of 14mm. Since the largest head diameter that meets specification is smaller

[2] Trandosky, S., P. D. Postak, A. I. Froimson, and A. S. Greenwald. "AComparison of the Dissociation Strength of Modular Acetabular Components."Clinical Orthopaedics and Related Research 1993; 296:154-60.

[3] ISO 7206-8: 1995(E). Implant for surgery – Partial and total hip joint prostheses. *"Endurance Performance of Stemmed Femoral Components with Application of Torsion"*.

than the smallest insert I.D. that meets specification, there will always be space for lubricants to get in between the head and the insert. This worst-case scenario is never expected *in vivo.*

In conclusion, the static and post fatigue torsional resistance demonstrated by the assembled ceramic insert and shell is greater than the maximum torque expected in vivo in an artificial joint of this nature.

Wear of Alumina Ceramic-on-Ceramic Hip Bearings

A wear test designed to replicate an *in vivo* condition, comparing the amount of wear debris produced by the 28mm ceramic-on-ceramic couple to that of the traditional couple of polyethylene and cobalt chrome was conducted.

The CMM data indicated that dimensional changes after 5 million cycles were still below the resolution of the CMM machine (2 µm). Weight loss and dimensional changes were too insignificant to be detected. There was a slight increase in surface roughness for both head and liner. The wear results conducted from this test showed that the ceramic on ceramic articulation surface produce no detectable wear after 5 million cycles.

Ring-on-Disk Test

The purpose of this test was to determine the wear resistance according to the Ring-on-Disk method (ISO Draft 6474).

The sponsor tested the device for 120 hours and the depth of the wear mark was below 1 µm. According to the results, the specimen met ISO Draft 6474 with respect to wear resistance allowing an average wear rate of $0.01 mm^3/h$.

Ceramic Insert Burst Test

The purpose of this test was to determine the minimum static fracture load for the smallest ceramic inserts (worst case). The ceramic insert size 28/37G was determined to be the worst case for the testing because it has the smallest cross sectional area (to resist static compressive loads) within the implant system under consideration.

The mean static axial compressive fracture load (79,836N) demonstrated by the ceramic inserts was 34.7 times greater than the hip stem compressive fatigue load recommended by ISO 7206-8[3,4]. When the ceramic head/ceramic liner constructs were loaded compressively to failure, it was the ceramic femoral heads that failed. The ceramic inserts failed when loaded by cobalt chromium femoral heads. This ceramic/cobalt chromium combination is not representative of a clinical situation. The ceramic heads and ceramic inserts both failed at loads significantly higher than physiological loads.

[4] ISO 7206-8: 1995(E). Implant for surgery – Partial and total hip joint prostheses. *"Endurance Performance of Stemmed Femoral Components with Application of Torsion"*.

TRANSCEND® Ceramic on Ceramic FEA Analysis of the Wright Medical Technology 36 mm Ceramic Femoral Head, Long

The purpose of this Finite Element Analysis was to compare the maximum stresses caused by axial compressive loading of the Wright Medical Technology 36 mm long ceramic femoral head with the Wright Medical Technology 32 mm long ceramic femoral head.

The 36 mm ceramic femoral head exhibits 10% lower maximum stress under comparable axial compressive loading than the 32 mm ceramic femoral head which is cleared for commercial use (K893685). This test demonstrated that a larger size head exhibits a lower stress on the acetabular insert than smaller heads.

TRANSCEND® Ceramic on Ceramic, Ceramic Insert Fatigue Test

The purpose of this test was to determine the static fracture load for the smallest insert after cyclic fatigue and to analyze the surfaces for evidence of crevice corrosion. Size 28/37G was determined to be the worst case for all the testing because it has the smallest amount of taper surface contact area within the implant system under consideration. The mean static axial compressive fracture load (78,600N) demonstrated by the ceramic inserts was 34.2 times greater than the hip stem compressive fatigue load recommended by ISO 7206-8. When the ceramic head/ceramic liner constructs were loaded compressively to failure, it was the ceramic femoral heads that failed. The ceramic inserts failed when loaded by cobalt chromium femoral heads. This ceramic/cobalt chromium combination is not representative of a clinical situation. The ceramic heads and ceramic inserts both failed at loads significantly higher than physiological loads.

Stereological Evaluation of the Porous Coating of the INTERSEAL® Acetabular Cup System

The purpose of this study was to characterize the structure of the ASTM F-67 porous coating of the acetabular cup system. Size 52mm acetabular shells were used for this evaluation.

The distance between particles and mean intercept length measured approximately 124 and 114 microns, respectively. These distances are in the range of 50 to 400 microns suggested as optimum for bone ingrowth by Bobyn et al[5].

Sterilization

TRANSCEND® ceramic femoral heads and ceramic liners are sterilized by ethylene oxide sterilization. The ETO sterilization process, as practiced by WMT, is validated and subsequently revalidated annually. ETO sterilization validation studies are conducted according to the requirements of AAMI/ISO 1135: Medical Devices-Validation and Routine Control of Ethylene Oxide Sterilization. The microbiological performance qualification aspects of the validation study incorporate the half cycle method of ethylene

[5] Bobyn, J. D., R. M. Pilliar, H. U. Cameron, and G. C. Weatherly. "The Optimum Pore Size for the Fixation of Porous-Surfaced Metal Implants by the Ingrowth of Bone." *Clinical Orthopaedics and Related Research* 1980; 150:263-70.

oxide sterilization validation. Wright Medical Technology's validation studies are based on the overkill sterilization approach to yield a minimum Sterility Assurance Level (SAL) of 10^{-6}. TRANSCEND® ceramic femoral heads and ceramic liners are sterilized in an ETO process designed to yield a SAL of 10^{-6}.

X. SUMMARY OF CLINICAL STUDIES

A. Published Literature

Published literature of early results of the Ceramic TRANSCEND® discuss significant improvement in average Harris Hip Scores and SF-12 scores. No fractures of the ceramic components were reported in these articles.[6,7]

B. Pivotal Clinical Study

The Ceramic TRANSCEND® Hip Articulation System pivotal clinical study was approved on November 4, 1996 and the first patient was implanted with the investigational device on April 7, 1997.

The study was a prospective, multi-center, non-masked clinical trial, comparing the Ceramic TRANSCEND® Hip Articulation System to the historical control group of the Whiteside Total Hip System, which was approved in 1990. Patients are currently being followed until the last patient enrolled was seen for his/her two-year exam. Patients were implanted with the Ceramic TRANSCEND® Articulation Hip System and a commercially cleared Wright Medical hip stem, including the following: BRIDGE®, PERFECTA®, EXTEND®, and Wright Choice hip stems.

Although the primary efficacy endpoint in the clinical study was the survivorship of the Ceramic TRANSCEND® Hip Articulation System as assessed at the two year postoperative interval, for the purpose of the clinical study, the primary efficacy endpoints included Harris Hip Score and radiographic assessments at 2 years, as well. In addition, patient satisfaction was assessed by the SF-12 at two years.

Complication rates were the primary safety endpoint.

Study Design

The study was a prospective, multi-center, historical control, clinical trial. The historical control group was later selected as the population from Whiteside Total Hip System clinical trial consisting of non-inflammatory degenerative joint disease cases. Study patients consisted of individuals over 21 years of age presenting for total hip arthroplasty due to osteoarthritis, congenital hip dysplasia, traumatic arthritis and avascular necrosis. A total of 329 procedures have been performed with the Ceramic TRANSCEND® device in the original clinical population (Original Clinical Population). An additional 630 procedures were implanted under Continued Access. The total number (Original Clinical

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[6] Garino, Jonathan P., M.D. "Modern Ceramic-on-Ceramic Total Hip Systems in the United States." *Clinical Orthopaedics and Related Research* 2000; 379:41-47.

[7] Murphy, Stephen B., M.D., and Wael K. Barsoum, M.D. "Ceramic-Ceramic Bearings in Total Hip Arthroplasty: Preliminary Clinical Results." *The Orthopaedic Journal at Harvard Medical School* 2001; 3:92-94.

Population and Continued Access) meeting the inclusion/exclusion criteria as required by the protocol is 959 procedures in 848 patients. Over a two-year period, 211 hip prostheses (179 patients) with metal femoral stems and plastic cups were implanted in the Whiteside Clinical Study.

Pivotal Clinical Patient Assessment

Each patient was evaluated at the immediate and 6, 12, and 24-month post-operative intervals, unless otherwise indicated by complications. At each follow-up visit, a Harris Hip Score and SF-12 was administered as well as obtaining AP and lateral radiographs. Radiographs were reviewed by the implanting surgeon. There were no pre-specified success/failure criteria in the clinical study.

Demographics

For the study population, there were a total of 965 procedures performed in 854 patients at 12 sites by 19 surgeons. Six of these patients did not meet study inclusion criteria (one procedure enrolled as a replacement for a previously implanted THR and five procedures performed in patients with rheumatoid arthritis). These six procedures are excluded from this analysis. Therefore, the primary analysis sample included 959 procedures for first hip replacements performed in 848 patients.

The patient accounting and Baseline Demographics are summarized in Tables 1 and 2. Note that there were 7 deaths, none of which were related to the study or to the device.

Table 1: Patient Accounting

Evaluation Interval	Original Clinical Patient Population (n=329)			Continued Access Population (n=630)		
	TFU	EFU	AFU (%)	TFU	EFU	AFU (%)
Pre-Op	329	329	100% (n=329)	630	630	100% (n=630)
6 months	329	323	93% (n=300)	602	602	71% (n=430)
12 months	329	321	91% (n=293)	443	442	53% (n=233)
24 months	329	321	94% (n=302)	151	150	0% (n=0)

TFU = Theoretical Follow-Up; EFU = Expected Follow-Up (Theoretical Follow-Up minus deaths and removals without replacement); AFU = Actual Follow-up

Table 2: Baseline and Demographics

Values	Total Study Procedures (n=959)	Whiteside Clinical Study (n=211)
Mean Age in years	51.4 years (range 20-80)	62.7 years (range 22-87)
Gender	595 (62%) Males 364 (38%) Females	112 (53%) Males 99 (47%) Females
Mean Body Mass Index (kg/m^2)	28.8 (range 17.7-65.8)	27.1 (range 22.8-40.9)
Diagnosis		
Osteoarthritis	692 (72.2%)	180 (85.3%)
Avascular Necrosis	189 (19.7%)	31 (14.7%)
Traumatic Arthritis	36 (3.8%)	0
Congenital Hip Dysplasia	42 (4.4%)	0
Mean Baseline Total HHS (range 1-100)	45.1 (range 8.3-95.9)	42.7 (range 11-79)
Mean Baseline Pain HHS (range 0-44)	12.9 (range 0-44)	13.2 (range 0-30)
Mean Baseline Harris ROM° (range 0-5)	3.8 (range -3.1-4.88)	4.1 (range not available)

Adverse Events

The adverse events related to total hip replacement surgery reported in the pivotal clinical study 959 patients are listed in Table 3.

Table 3: Reported Adverse Events				
Event	**Clinical Study (n=959)**		**Whiteside Clinical Study (n=211)**	
Systemic	**Freq.**	**% of Pop.**	**Freq.**	**% of Pop.**
Deaths	9	0.9%	0	0%
Pulmonary Embolism	2	0.2%	2	0.9%
Deep Vein Thrombosis	4	0.4%	0	0%
Local	**Freq.**	**% of Pop.**	**Freq.**	**% of Pop.**
Breakage/Fracture of Component[1]	5	0.5%	2	0.9%
Dislocation (single) of Component[2]	8	0.8%	3	1.4%
Dislocation (recurrent) of Component[3]	2	0.2%	0	0%
Femoral Fracture	18	1.9%	9	4.3%
Hematoma	2	0.2%	0	0%
Heterotopic Ossification	1	0.1%	1	0.5%
Infection: Deep, Early < 1year	2	0.2%	0	0%
Infection: Deep, Late >1 year	1	0.1%	0	0%
Infection: Superficial	7	0.7%	0	0%
Loosening of Component	3	0.3%	2	0.9%
Migration of Component	2	0.2%	0	0%
Persistent Foot Drop	2	0.2%	0	0%
Pain	10	1.0%	0	0%
Perforation of Femur During Reaming	2	0.2%	0	0%
Wear of Component	1	0.1%	0	0%
Subsidence of Component	3	0.3%	2	0.9%
Soft Tissue Trauma	0	0%	0	0%
Wound Problems	2	0.2%	0	0%
Other Local Complication[4]	10	1.0%	0	0%
Local - Hip	**Freq.**	**% of Pop.**	**Freq.**	**% of Pop.**
Trochanteric Bursitis	16	1.7%	1	0.5%
Trochanteric Non-union	0	0%	0	0%
Trochanteric Avulsion	4	0.4%	0	0%

Notes:

[1.] Clinical Study : Chipping of ceramic acetabular liner during placement requiring intraoperative revision.
Whiteside Clinical Study: Broken metal peg of acetabular cup

[2.] 2 were revised for this reason

[3.] 1 was revised for this reason.

[4.] Consisted of: 3 cases of irritation/inflammation; 2 cases where patients fell; 1 case of component mismatch; 1 case of liner malposition; 1 case where the acetabular shell seated too deeply in the reamed cavity; 1 case of hip flexor weakness; and 1 case where the anterior abductor pulled off. None of these complications were related to the study hip or the procedure.

Efficacy results

Table 4: Efficacy Results - HHS

Primary Efficacy Assessment	Original Patient Population (n=329)[1]	Continued Access Population (n=630)[2]	Whiteside Clinical Study (n=211)
Preoperative mean HHS (range)	44.8 (13-89)	45.2 (8-96)	42.7 (11-79)
2 year postop mean HHS (range)	94.8 (34-100)	88.1 (17-100)	92.7 (39-100)
% Excellent/Good Results (HHS 80-100 points) at 2 years postop	92.2%	76.9%	88.2%

Notes:

[1.] Original clinical population includes the first 329 procedures enrolled in the clinical study. This includes replacements and removals prior to 24 months (n=9), deaths prior to 24 months (n=7), and cases in which only a partial Harris Hip Score at 24 months or later was available (n=4)

[2] The *Continued Access* sample (N=630) includes procedures performed after the original clinical population without Month 24+ outcomes. Therefore, outcomes reported were defined on the basis of Last Observation Carried Forward (LOCF) and represent the latest clin ical results available for that procedure.

Any Radiographic Lucency

Radiolucencies were recorded at each follow-up visit based on if they involved the entire Gruen zone (7 AP femoral zones, 7 lateral femoral zones, 3 AP acetabular zones, and 3 lateral acetabular zones). Table 5 summarizes these results.

Table 5: Any Radiolucency

Lucency	Original Study Population (n=329)	Whiteside Clinical Study (n=211)
Femoral	18 (5.5%)	66 (31.3%)
Acetabular	9 (2.8%)	56 (26.5%)
Overall	22 (6.8%)	77 (36.5%)

In addition, any subsidence was reported for the original study population for 0.9% of the femoral stems and 0.3% of the acetabular cups. In the Whiteside Clinical Study there were two instances of femoral stem subsidence (1.0%).

Implant Survivorship

Implant sur vivorship was the pre-specified primary endpoint in the pivotal clinical study of the Ceramic TRANSCEND® hip. Kaplan-Meier cumulative survivorship is shown in Tables 6 and7 for the Ceramic TRANSCEND® and the Whiteside hips over time.

The cumulative Kapla n-Meier survivorship values for the femoral or acetabular component are shown in tables 6 and 7 based on the longest duration of follow-up available in each study cohort.

Table 6: Ceramic TRANSCEND® Implant Survivorship

Interval	Number Entering Interval	Number Withdrawn	Number Revised in Interval	Cumulative Survival	Standard Error
12 months	528	69	8	0.9909	0.0041
24 months	279	78	1	0.9876	0.0066
36 months	1	0	0	0.9308	0.0562

Table 7: Whiteside Clinical Study Implant Survivorship

Interval	Number Entering Interval	Number Withdrawn	Number Revised in Interval	Cumulative Survival	Standard Error
12 months	234	8	3	0.9870	0.0074
24 months	223	70	1	0.9817	0.0090
36 months	152	103	1	0.9719	0.0131
48 months	48	34	3	0.8779	0.0481
60 months	11	11	0	0.8779	0.0481

Revisions and Removals

Eleven devices out of the 959 primary patients enrolled in the trial have been revised or removed. Table 9 summarizes the clinical information pertaining to these cases.

Patient Success Criteria

Table 8 describes the proportion of patients meeting individual clinical success criteria at 2 years postoperatively.

Table 8: Patient Success Criteria at 2 Years

Patient Success Criteria	Original Patient Population (n=329)[1]	Whiteside Clinical Study (n=211)
Absence of Revision (%)	96.7% (n=318)	98.1% (n=207)
Total HHS ≥ 70	96.8% (n=318)	95.3% (n=201)
No Complete Radiolucencies[2]	99.7% (n=328)	88.5% (n=184)

Notes:

[1] The *Original Patient Population* sample includes procedures in the *Complete Endpoint* (N=309) sample plus procedures with revisions, replacements, or removals prior to Month 24 (N=9); who died prior to Month 24 (N=7); or who had only a partial Harris Hip Score assessment at Month 24 or later (N=4). This sample was constructed in order to facilitate an analysis of efficacy and safety endpoints for hips that were at-risk for a complication and that 'completed the study'. For *Complete Follow-up* procedures (N=329), the Month 24+ endpoint was defined as the Month 24 value and if not available, values after Month 24 were used. Original clinical study population includes the first 329 procedures enrolled in the clinical study. This includes replacements and removals prior to 24 months (n=9), deaths prior to 24 months (n=7), and cases in which only a partial Harris Hip Score at 24 months or later was available (n=4)

[2] Absence of complete radiolucency was determined by radiographic evaluation for four views: acetabular AP view (3 regions), acetabular lateral view (3 regions), femoral stem AP view (7 regions), and femoral stem lateral view (7 regions). Complete radiolucency in a view was defined to be present if there was any radiolucency present in all zones comprising that view. Absence of complete radiolucency was defined to be present if none of these four views had complete radiolucency.

Table 9: Summary of Revisions and Removals

Procedures	Age/ Gender	Diagnosis	Duration of Implantation	Reason for Revision/Removal
Revision of acetabular component with bone graft and cage implantation	50/F	AVN	84 days	Migration of acetabular component
Revision of femoral head with a longer neck	29/F	Congenital Hip Dysplasia	1 day	Dislocation
Replaced acetabular component to larger size (32mm) and replaced femoral head to 35mm	43/M	Severe osteoarthritis with mild hip dysplasia	1 day	Dislocation
Replacement of acetabular component, liner, and femoral head. Repair of abductor mechanism.	62/M	Osteoarthritis	38 days	Persistent dislocation following closed reduction; trochanteric fracture with avulsion of abductors
Revision followed by removal and girdlestone procedure	51/M	Traumatic arthritis	210 days	Deep infection and stitch abscess
Replacement of acetabular liner	36/F	Congenital hip dysplasia	3 days	Acetabular liner disassociated from shell
Replacement of acetabular liner and femoral head	41/M	Osteoarthritis	14 days	Increasing pain, suspected infection
Replacement of acetabular liner and femoral head	58/M	Avascular Necrosis	953 days	Excessive wear due to impingement on acetabular cup rim
Replacement of femoral head from 32mm to 28mm	50/M	Osteoarthritis	1 day	Liner/head size mismatch noted on postoperative film
Replacement of (uncemented) femoral stem to cemented stem	56/M	Osteoarthritis	657 days	Pain and progressive subsidence due to undersized (uncemented) femoral stem
Replacement of femoral stem and head	56/F	Osteoarthritis	786 days	Femoral component loosening

XI. CONCLUSIONS DRAWN FROM THE STUDIES

The preclinical and clinical data provides reasonable assurance that the Ceramic TRANSCEND® Hip Articulation System is safe and effective for total hip replacement in patients with osteo/degenerative arthritis, avascular necrosis, and related diagnoses.

XII. PANEL RECOMMENDATIONS

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA application was not referred to the Orthopedic Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CDRH DECISION

The applicant has adequately submitted all answers to the FDA's questions and comments for their PMA application. The applicant has agreed to conduct a post-approval study to further evaluate the long-term safety and effectiveness of the device. Five-year follow-up data will be collected on patients enrolled in the clinical study.

Therefore, since all the conditions of approval have been met, FDA finds in favor of approval of the Ceramic TRANSCEND® Hip Articulation System. The applicant's manufacturing facilities were inspected and determined to be in compliance with the Quality System Regulation (21 CFR Part 820).

FDA issued an approval letter to the applicant on February 3, 2003.

XIV. APPROVAL SPECIFICATIONS

Directions for Use: See the Device Labeling

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the label

Post-Approval Requirements and Restrictions: See Approval Order