

## SUMMARY OF SAFETY AND EFFECTIVENESS DATA

### I. GENERAL INFORMATION

Device Generic Name:	Total Hip System, Ceramic Articulation
Device Trade Name:	Stelkast Surpass™ Acetabular System
Applicant's Name and Address:	Stelkast Company 200 Hidden Valley Road McMurray, PA 15317
Premarket Approval (PMA) Number:	P040051
Date of Panel Recommendation:	None
Date of Notice of Approval to the Applicant:	May 12, 2006

The approval of the Stelkast Surpass Acetabular System is being granted in part due to a licensing agreement with CeramTec, who owns the rights to the PMA for the TRANSCEND Ceramic Hip System (P010001) and also distributes the ceramic components used in both the Surpass Acetabular System and TRANSCEND System. The Surpass Acetabular System uses the same ceramic femoral heads and ceramic acetabular liners as the TRANSCEND System while employing Stelkast's own acetabular shells and femoral stems. A component comparison along with preclinical test results were used to demonstrate that the Surpass Acetabular System performs similarly to the TRANSCEND device. Therefore, the clinical data referenced from the PMA for the TRANSCEND System has been used to predict the clinical outcome of the Surpass Acetabular System.

### II. INDICATIONS FOR USE

The Stelkast Surpass Acetabular System is indicated for cementless use in primary total hip arthroplasty in skeletally mature individuals 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
- Insufficient bone stock to allow appropriate insertion and fixation of the prosthesis
- Insufficient soft tissue integrity to provide adequate stability
- Muscle laxity or inadequate soft tissue for proper function and healing
- Neuromuscular disorders that do not allow control of the affected joint
- Skeletally immature patients

#### IV. WARNINGS and PRECAUTIONS

The warnings and precautions can be found in the Surpass Acetabular System's package insert (Instructions for Use).

#### V. DEVICE DESCRIPTION

The Stelkast Surpass Acetabular System is a modular, ceramic-on-ceramic total hip replacement system consisting of alumina ceramic femoral heads and acetabular liners, titanium alloy acetabular shells, titanium alloy femoral stems, and optional titanium alloy cancellous bone screws. The bearing surfaces consist of Stelkast Ceramic Femoral Heads and corresponding sizes of Stelkast Surpass Acetabular Liners. Both components are manufactured from high-purity dense aluminum oxide ceramic (a.k.a. alumina -  $Al_2O_3$ ) by CeramTec. CeramTec markets this alumina ceramic under the brand name BioloX<sup>®</sup> forte. The alumina conforms to ASTM F603 and ISO 6474 material specifications.<sup>1,2</sup>

##### **Femoral Heads**

The alumina Stelkast Ceramic Femoral Heads are offered in outer diameters of 28mm and 32mm with three neck lengths each (short / -3.5mm, medium / 0mm, and long / +3.5mm). These heads have the standard CeramTec 12/14 tapers.

##### **Ceramic Liners (or Inserts)**

The alumina Stelkast Surpass Acetabular Liners are available in three sizes (28-46, 32-52, and 32-58). These designations (e.g., 28-46) correspond to the inner diameter of the liner and the outer diameter of the smallest compatible acetabular shell. The liner that is used with the 28mm femoral head is referred to by Stelkast as the 28-46 liner and is designed to fit shells of 46, 48, and 50mm outer diameter only. Two liners are available for use with a 32mm head, one (the 32-52 liner) that is designed to fit shells of 52, 54, and 56mm outer diameter, and another (32-58 liner) designed to fit shells ranging in size from 58 to 72 in 2mm increments.

The alumina liners are designed to fit by impaction into the acetabular shells. Retention is by means of a tapered interference fit (Morse-type taper) and controlled surface finish.

##### **Acetabular Shells**

The Stelkast Surpass Acetabular Shells are available in 14 sizes with outer diameters ranging from 46 to 72mm in 2mm increments. The inner geometries accommodate the 28-46 liner (3 shells – 46mm, 48mm, and 50mm diameter), the 32-52 liner (3 shells – 52mm, 54mm, and 56mm diameters), and the 32-58 liner (8 shells – 58mm to 72mm diameters). The 46 mm shell includes 2 screw holes for added fixation,

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<sup>1</sup> ASTM F603, Standard Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Applications

<sup>2</sup> ISO 6474, Implants for surgery – Ceramic materials based on high purity alumina

whereas all other shells include a cluster of 3 screw holes. These shells are intended for cementless fixation, with available supplemental screw fixation when needed.

The shells are manufactured from wrought or forged Ti-6Al-4V ELI alloy (per ASTM F136 or ASTM F620, respectively<sup>3,4</sup>), and are hemispherical with a 17° rim flare. The outer surfaces of the shells are porous-coated with plasma-sprayed commercially pure titanium powder, per ASTM F1580.<sup>5</sup> The inner surface has a female taper to mate with the male taper of the ceramic liner.

The flat face of the equatorial rim of the Surpass shell features 4 “dimples” that accommodate the ceramic liner extraction instrument. The Surpass shell also features an equatorial lip around the circumference of the outer rim of the shell.

In addition, the shells include an apical threaded hole to accommodate the shell inserter instrument.

### **Cancellous Bone Screws**

Stelkast 6.5mm acetabular cancellous bone screws that vary in length from 15mm to 60mm may be used for added fixation. These self-tapping screws are manufactured from wrought titanium alloy Ti-6Al-4V according to ASTM F-1472.<sup>6</sup> These screws have been modified from previous Stelkast designs by reducing the head profile to prevent impingement with the ceramic liners.

### **Femoral Stems**

The Surpass Acetabular System will be used with the Protract, ProClass, and Provident hip stems from Stelkast. These stems are intended for press-fit cementless use. Similar versions of these stems have previously been cleared via 510(k) for use with metal/poly articulating bearing couples. Minor modifications have been made to the taper of the stem trunnions that mate with the ceramic femoral head in order to conform to the dimensions, tolerances and surface condition required for the CeramTec ceramic heads. Each of the three identified stems is available with a standard and lateral offset. In addition, the Protract stem is available in a hydroxyapatite (HA) coated version.

The Provident and Protract stems are made from Ti-6Al-4V ELI alloy (per ASTM F136 wrought and F620 forged), while the ProClass stems are made from Ti-6Al-7Nb alloy (per ASTM F1295 wrought and ASTM F620 forged).<sup>7</sup>

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<sup>3</sup> ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications

<sup>4</sup> ASTM F620, Standard Specification for Alpha Plus Beta Titanium Alloy Forgings for Surgical Implants

<sup>5</sup> ASTM F1580, Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants

<sup>6</sup> ASTM F1472, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium Alloy for Surgical Implant Applications

<sup>7</sup> ASTM F1295, Standard Specification for Wrought Titanium-6 Aluminum-7 Niobium Alloy for Surgical Implant Applications

## 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. Other bearing surface alternatives used in total hip replacement include: ceramic on polyethylene, metal on metal, and metal on polyethylene bearing articulations.

## VII. MARKETING HISTORY

The Stelkast Surpass Acetabular System has not been previously marketed.

## VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

The Stelkast Surpass Acetabular System is similar to the previously approved TRANSCEND Ceramic Hip System (P010001). Stelkast references the clinical data from P010001, under a licensing agreement, as clinical support for the Stelkast Surpass Acetabular System. The clinical data are relevant because the two systems use identical ceramic components (i.e., alumina ceramic femoral heads and acetabular liners). Additionally, a system comparison between the Stelkast Surpass Acetabular System and the TRANSCEND Ceramic Hip System was performed to demonstrate that the systems perform similarly enough on the bench that the clinical data referenced can be used to predict the clinical outcomes for the Stelkast Surpass Acetabular System.

Please refer to Table 3 in Section X (Summary of Clinical Studies) for a tabulation of adverse events that occurred in the referenced study (P010001).

### **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 titanium or hydroxyapatite 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 Surpass Acetabular System**

1. Wear of the ceramic 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 or chipping of the femoral head or acetabular liner.

**IX. SUMMARY OF PRECLINICAL STUDIES**

The results of the preclinical testing listed below demonstrate that the Stelkast Surpass Acetabular System performs similarly on the bench to the CeramTec TRANSCEND Ceramic Hip System (P010001). The Stelkast Surpass Acetabular System uses the same ceramic femoral heads and ceramic acetabular liners that are used in the TRANSCEND System. The Stelkast Surpass Acetabular System uses Stelkast's own metal acetabular shells and femoral stems to comprise the system. The comparability of the Stelkast Surpass Acetabular System and the TRANSCEND System was demonstrated through side-by-side component comparison and a comparison of preclinical test results.

A battery of preclinical laboratory tests were conducted on the alumina ceramic material used to make the ceramic components. It conforms to the ASTM F603 and ISO 6474 requirements and has been shown to be safe and effective. The metal components that comprise the rest of this system are made from materials that have been used for many years in total hip replacement (THR) surgery. These components are currently on the market as part of other Stelkast hip systems.

Preclinical laboratory studies were conducted by CeramTec (except where noted) in support of the design of the Stelkast Surpass Acetabular System. Worst case conditions were established for each component for testing purposes and evaluation. It was determined that the worst-case condition would be achieved for ceramic heads

by testing the smallest diameter head in the long-neck (+3.5mm) configuration. For the acetabular liner, finite element analysis was used to determine that the worst-case condition would be realized by testing the 28mm liner in the corresponding 46mm shell. This product combination also represents the worst case condition for liner push-out testing and rotational stability testing, because its taper contact area is the lowest in the Stelkast Surpass Acetabular System.

#### **Ceramic Femoral Head Testing**

All testing of the ceramic femoral heads was conducted in accordance with the January 10, 1995, FDA *Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems (FDA Guidance)*. The identified acceptance criteria in each test below are identical to the criteria used to qualify the same femoral heads of the TRANSCEND system.

#### **Ceramic Head Burst Testing**

Static burst testing of ceramic ball heads used for the Stelkast Surpass Acetabular System was conducted according to the method of ISO 7206-10.<sup>8</sup> Because ProClass stems are made from Ti-6Al-7Nb alloy and Provident stems are made from Ti-6Al-4V ELI alloy, burst testing was conducted using specimens of each trunnion to establish which of the trunnions would result in the lowest burst test values and to guide subsequent testing. Seven tests were performed using 28-12/14L ceramic ball heads and trunnions from Stelkast ProClass stems and seven tests were performed using trunnions from Stelkast Provident stems. Cross-head speed was 2 mm/min. These tests showed that the lowest burst test values (average 46 kN, minimum 40 kN) were obtained using the ProClass trunnions. These values meet the requirements of the FDA Guidance. Based on this result, subsequent tests were performed using ProClass trunnions.

#### **Ceramic Head Fatigue Testing**

Fatigue testing of three 28-12/14L ceramic ball heads on ProClass trunnions was conducted. The applied load was cycled from 14.0 to 0.5 kN at a frequency of 10 Hz in Ringers solution at ambient temperature. All specimens reached 10 million cycles without failure or formation of macroscopically detectable defects, meeting the requirements of the FDA Guidance.

Following fatigue testing, burst testing of the three samples was performed, with a resulting average burst test value of 35 kN and a minimum value of 25 kN. These values exceed the 20 kN requirement for the post-fatigue burst strength set by the FDA Guidance.

#### **Ceramic Head Pull-off Testing**

Five 28-12/14L ceramic ball heads were tested for pull-off loads using ProClass trunnions, testing at a cross-head speed of 2 mm/min. Acceptance criterion was

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<sup>8</sup> ISO 7206-10, Implants for surgery – Partial and total hip joint prostheses – Part 10: Requirements, classification and designation of dimensions of bores and cones for prostheses with a modular head

defined as > 250 N. The average pull-off load was 1518 N and the minimum was 1219 N. These values exceeded the acceptance criteria as defined in the CeramTec Qualification Program for Ceramic Ball Heads.

#### Ceramic Head Rotational Stability Testing

Three 28-12/14L ceramic ball heads were tested for rotational stability using ProClass trunnions. Acceptance criterion was defined as > 500 N-cm. The average torque at rotation between the head and trunnion was 1525 N-cm and the minimum was 1159 N-cm. These values exceeded the acceptance criteria as defined in the CeramTec Qualification Program for Ceramic Ball Heads.

#### Ceramic Liner Testing

Acetabular shell/liner testing was conducted per CeramTec Qualification Program for Ceramic Inserts. The identified acceptance criteria in each test below are identical to the criteria used to qualify the same components of the TRANSCEND system.

#### FEA Comparison of Shell/Liner Assemblies

Finite Element Analysis (FEA) was conducted to examine and compare the stresses in the 28/37, 32/41, and 32/44 acetabular shell and liner constructs at an axial load of 8 kN and 40 kN. Results of the analysis indicated that the increased cross-sectional thickness of the 32/44 liners had a negligible effect on stress, and the 28/37 liners exhibited the highest stresses and are considered worst case for static and dynamic loading. As a result, all subsequent physical testing was conducted using the 28/37 liners.

#### Ceramic Liner Burst Testing

Static burst testing of 28mm BioloX *forte* ceramic acetabular liners contained in the corresponding Stelkast 46mm acetabular shells used for the Stelkast Surpass Acetabular System was conducted using CeramTec procedures. Seven sets of components were tested, resulting in an average burst test value of 65 kN and a minimum of 62 kN. These values surpass the acceptance criteria of 46 kN (mean) and 25 kN (minimum). These values are also higher than those obtained in burst testing of ceramic heads. The ceramic heads apply the load to the liner in actual clinical use, and are therefore the weakest link.

#### Ceramic Liner Fatigue Testing

Fatigue testing of three 28mm BioloX *forte* ceramic liners in Stelkast 46mm acetabular shells was conducted at EndoLab GmbH. Loading was from 14.0 to 0.5 kN at a frequency of 10 Hz in Ringers solution at ambient temperature. The acceptance criterion was defined as the ability to survive 20 million cycles at 14 kN with no macroscopically visible signs of failure. All specimens reached 20 million cycles without failure or formation of macroscopically detectable defects.

Following fatigue testing, burst testing of the three samples was performed, with a resulting average burst test value of 47 kN and a minimum of 37 kN. These values

exceeded the acceptance criterion of 20 kN established for the post-fatigue burst strength.

#### Ceramic Liner Rotational Stability Testing

Three 28mm BioloX *forte* ceramic liners in Stelkast 46mm acetabular shells were tested for rotational stability. The acceptance criterion was defined as  $\geq 400$  N-cm. The resulting average torque at rotation between the liner and shell was 1472 N-cm, with a minimum of 1099 N-cm. All tested samples exceeded the established acceptance criterion.

#### Ceramic Liner Push-out Testing

Five 28mm BioloX *forte* ceramic liners in Stelkast 46mm acetabular shells were tested for static push-out loads, testing at a cross-head speed of 2 mm/min. The acceptance criterion was defined as  $\geq 200$  N. Average push-out load was 458 N, with a minimum of 258 N. All tested samples exceeded the established acceptance criterion.

Post-fatigue push-out testing was also conducted. Axial compressive fatigue testing was conducted for 2000 cycles at 14 kN. The mean post-fatigue push-out load was 7.05 kN (s.d. 0.18), which is well above the 200 N acceptance criterion. Fatigue testing actually increases the push-out resistance of the ceramic liner as the repetitive loading regimen of 14 kN incorporates a higher compressive load than the static test which incorporated a single 2 kN compressive preload.

#### Ceramic Liner Lever-out Testing

Three 28mm BioloX *forte* ceramic liners in Stelkast 46mm acetabular shells were tested for lever-out torque. The acceptance criterion was defined as  $> 3000$  N-cm. The average lever-out force applied was 665 N with a minimum applied force of 437 N. Average lever-out torque was 6783 N-cm, with a minimum of 4459 N-cm (s.d. 2178 N-cm). All test samples exceeded the established acceptance criterion.

#### Range of Motion

A computer aided design (CAD) range of motion (ROM) analysis of the total hip joint construct was performed for the Surpass system. ROM was measured by moving the stem about the center of rotation of the femoral head and liner until impingement occurred between the stem and acetabular component. Measurements were made with each size and type of femoral stem in combination with each size acetabular shell, acetabular liner, and the corresponding femoral head diameter including each available offset. For the 28mm head/liner construct the acceptance criterion was defined as  $\geq 117^\circ$ , for the 32mm head/liner construct the acceptance criterion was defined as  $\geq 124^\circ$ . These acceptance values were based on the minimum ROM values for the TRANSCEND System. The minimum ROM for the 28mm head/liner construct of the Surpass System was  $132^\circ$ , and the minimum ROM for the 32mm head/liner construct was  $136^\circ$ . As with the TRANSCEND system the worst-case construct was the 28mm head/liner with the shortest neck offset (-3.5 mm). All construct combinations exceeded the established acceptance criteria.

### Wear of Alumina Ceramic-on-Ceramic Hip Bearings

PMA P010001, incorporated by reference, includes results of 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. This test is relevant to the Stelkast submission since the ceramic components of the reference submission and the Stelkast submission are identical.

The data from P010001 indicated that dimensional changes for the ceramic components after five million cycles were still below the resolution of the coordinate measuring system (2  $\mu\text{m}$ ). 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 surfaces used for the Stelkast Surpass Acetabular System produce no detectable wear after five million cycles.

### Ring-on-Disk Test

PMA P010001 includes results of a ring-on-disk test conducted according to ISO standard 6474. The device was tested for 120 hours and the depth of the wear mark was below 1  $\mu\text{m}$ . According to the results, the specimen met ISO 6474 with respect to wear resistance, allowing an average wear rate of 0.01mm<sup>3</sup>/h.

### Femoral Stem Fatigue Testing

Femoral stem fatigue testing was performed on three of the subject femoral stems. Testing was conducted in accordance with ISO 7206-4 and 7206-8.<sup>9,10</sup> As per ISO 7206-8 all three stems survived 5 million cycles at 517 lbs (2300 N) without failure, thus exceeding the acceptance criterion for this test.

### Sterilization

Sterilization of Stelkast Surpass Acetabular System ceramic femoral heads and acetabular liners, and titanium alloy acetabular shells, stems, and bone screws, will be accomplished by means of Co<sup>60</sup> gamma irradiation at a dose of 25 kGy (2.5 Mrad) minimum. Sterilization was validated by the bioburden method, according to ISO 11137 *Sterilization of health care products - Requirements for validation and routine control -- radiation sterilization*, using AAMI TIR27 *Sterilization of health care products – Radiation sterilization – substantiation of 25kGy as a sterilization dose – Method VD<sub>max</sub>*. The sterility assurance level (SAL) that was met is 10<sup>-6</sup>. Sterility and package integrity testing supports a sterile package shelf life of 10 years for this combination of components, packaging and sterilization method.

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<sup>9</sup> ISO 7206-4, Implants for surgery – Partial and total hip joint prostheses – Part 4: Determination of endurance properties of stemmed femoral components with application of torsion

<sup>10</sup> ISO 7206-8, Implants for surgery – Partial and total hip joint prostheses – Part 8: Endurance performance of stemmed femoral components with application of torsion

## X. SUMMARY OF CLINICAL STUDIES

### **Data Incorporation by Reference**

As previously stated, the Stelkast Surpass Acetabular System is similar to the previously approved TRANSCEND Ceramic Hip System (P010001). Stelkast references the clinical data from P010001, under a licensing agreement, as clinical support for the safety and effectiveness of the Stelkast Surpass Acetabular System. The clinical data are relevant because the ceramic femoral heads and ceramic acetabular liners of the Stelkast Surpass Acetabular System are identical to those of the previously approved system. The Stelkast Surpass Acetabular System uses Stelkast's own acetabular shells (designed to mate with the ceramic liners) and a subset of Stelkast's available femoral stems. The two systems were shown to perform similarly in bench testing.

### **Published Literature**

Published literature on early results of the TRANSCEND Ceramic Hip System discusses significant improvement in average Harris Hip Scores and SF-12 scores when compared to pre-operative scores. No fractures of the ceramic components were reported in these articles.<sup>11,12</sup>

### **Pivotal Clinical Study**

The study was a prospective, multi-center, non-masked clinical trial of 959 procedures in 848 patients, comparing the referenced ceramic hip system to a historical control group.

Although the primary efficacy endpoint in the clinical study was the survivorship of the referenced ceramic hip 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 two 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 implanted with a metal on polyethylene hip 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 were performed with the referenced ceramic hip system in the original clinical population (Original Clinical Population).

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<sup>11</sup> 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.

<sup>12</sup> 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.

An additional 630 procedures were implanted under Continued Access. The total number (Original Clinical 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 control group.

**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 total hip replacement (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 nine deaths, none of which was 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)	Historical Control Group (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 <sup>2</sup> )	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, degrees (range 0-5)	3.8 (range 3.1-4.88)	4.1 (range not available)

**Safety & Effectiveness Data****Safety Results**

The adverse events related to total hip replacement surgery reported in the pivotal clinical study of 959 procedures in 848 patients are listed in Table 3.

**Table 3: Reported Adverse Events**

Event	Ceramic TRANSCEND Clinical Study (n=959)		Historical Control Group (n=211)	
	Freq.	% of Pop.	Freq.	% of Pop.
<b>Systemic</b>				
Deaths	9	0.9%	0	0%
Pulmonary Embolism	2	0.2%	2	0.9%
Deep Vein Thrombosis	4	0.4%	0	0%
<b>Local</b>	<b>Freq.</b>	<b>% of Pop.</b>	<b>Freq.</b>	<b>% of Pop.</b>
Revisions/Removals <sup>1</sup>	11	1.1%	8	3.8
Breakage/Fracture of Component <sup>2</sup>	5	0.5%	2	0.9%
Dislocation (single) of Component <sup>3</sup>	8	0.8%	3	1.4%
Dislocation (recurrent) of Component <sup>4</sup>	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 < 1 year	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 <sup>5</sup>	10	1.0%	0	0%
<b>Local - Hip</b>	<b>Freq.</b>	<b>% of Pop.</b>	<b>Freq.</b>	<b>% of Pop.</b>
Trochanteric Bursitis	16	1.7%	1	0.5%
Trochanteric Non-union	0	0%	0	0%
Trochanteric Avulsion	4	0.4%	0	0%

**Notes:**

<sup>1</sup> See details in the following Table 4 for n=959.

<sup>2</sup> Clinical Study: Chipping of ceramic acetabular liner during placement requiring intraoperative revision.

Historical Control Group: Broken metal peg of acetabular cup

<sup>3</sup> 2 were revised for this reason

<sup>4</sup> 1 was revised for this reason.

<sup>5</sup> 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.

### Revisions and Removals

Eleven devices out of the 959 procedures in the trial have been revised or removed. Table 4 summarizes the clinical information pertaining to these cases.

**Table 4: 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

### Efficacy Results

Table 5, below, shows the mean and range of Harris Hip Scores for each study cohort preoperatively and two years postoperatively.

**Table 5: Efficacy Results - HHS**

Primary Efficacy Assessment	Original Patient Population (n=329) <sup>1</sup>	Continued Access Population (n=630) <sup>2</sup>	Historical Control Group (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:**

<sup>1</sup> 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)

<sup>2</sup> 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 clinical 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 (seven AP femoral zones, seven lateral femoral zones, three AP acetabular zones, and three lateral acetabular zones). Table 6 summarizes these results.

**Table 6: Any Radiolucency**

Lucency	Original Study Population (n=329)	Historical Control Group (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 historical control group there were two instances of femoral stem subsidence (1.0%).

### Implant Survivorship

Implant survivorship was the pre-specified primary endpoint in the pivotal clinical study of the referenced ceramic hip system. Kaplan-Meier cumulative survivorship is shown in Tables 7 and 8 for the referenced ceramic hip system and the historical control group over time.

The cumulative Kaplan-Meier survivorship values for the femoral or acetabular component are shown in Tables 7 and 8 based on the longest duration of follow-up available in each study cohort.

**Table 7: Referenced Ceramic Hip System 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 8: Historical Control Group 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

**Patient Success Criteria**

Table 9 describes the proportion of patients meeting individual clinical success criteria at two years postoperatively.

**Table 9: Patient Success Criteria at 2 Years**

Patient Success Criteria	Original Patient Population (n=329) <sup>1</sup>	Whiteside Clinical Study (n=211)
Absence of Revision (%)	96.7% (n=318)	98.1% (n=207)
Total HHS $\geq$ 70	96.8% (n=318)	95.3% (n=201)
No Complete Radiolucencies <sup>2</sup>	99.7% (n=328)	88.5% (n=184)

**Notes:**

<sup>1</sup> 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).

<sup>2</sup> 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.

## **XI. CONCLUSIONS DRAWN FROM THE STUDIES**

The preclinical and referenced clinical data provide reasonable assurance that the Stelkast Surpass Acetabular System is safe and effective for total hip replacement in patients with osteo/degenerative arthritis, avascular necrosis, and related diagnoses.

A system comparison analysis between the Stelkast Surpass Acetabular System and the TRANSCEND Ceramic Hip System (P010001) demonstrated that the systems perform similarly on the bench and that the clinical data referenced in Section X can be used to predict the clinical outcomes for the Surpass Acetabular System.

## **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 preclinical data and similarities in device design to the previously approved ceramic hip system (P010001) provide reasonable assurance that the Stelkast Surpass Acetabular System is safe and effective when used as directed for cementless use in primary total hip arthroplasty in skeletally mature individuals with noninflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, congenital hip dysplasia, and traumatic arthritis.

In addition, the applicant has agreed to conduct a 10 year post-approval study to evaluate the long term safety and effectiveness of the Stelkast Surpass Acetabular System. The study will enroll 300 patients, of which a minimum of 175 patients will be followed out to five years and a minimum of 100 patients will be followed out to 10 years. During the first five years of the study, clinical (HHS, adverse events), radiographic, patient self-assessment (SF-12), and patient satisfaction (survey) information will be collected for each subject. For the sixth through the tenth postoperative years, patients will be asked to return an outcomes questionnaire designed to determine the survivorship status of their hip replacement.

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 order on May 12, 2006.

#### 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 labeling.

Post-Approval Requirements and Restrictions: See Approval Order.