510(k) Summary

Manufacturer: StelKast, Inc.
200 Hidden Valley Road
McMurray, PA 15317

MAR 2 4 2011

Device Trade Name: EXp Acetabular Shell Liner

Contact: Mr. Donald A. Stevens
Vice Chairman
(888) 273-1583

Prepared by: Musculoskeletal Clinical Regulatory Advisers, LLC
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Washington, DC 20005
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Date Prepared: March 14, 2011

Common Name: Acetabular Shell Liner

Classification: 21 CFR 888.3358, Hip joint metal/polymer/metal semiconstrained porous-coated uncemented prosthesis

Class: II

Product Codes: OQG, OQH, OQI, LPH, LWJ, JDI, MAY, LZO

Indications For Use:
The EXp Acetabular Shell Liner is intended for use in reconstruction of the articulating surface of the acetabular portion of the hip that is severely disabled and/or very painful resulting from:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip Arthroplasty.

Cemented and Uncemented Applications

Device Description:
The EXp Acetabular Shell Liner is made of polyethylene to which Vitamin E has been added. It is available in both hooded and non-hooded options. The liner is part of a complete total hip system and will be used in conjunction with an acetabular shell, femoral head and femoral stem in total hip arthroplasty. The femoral heads which are to be mated with the EXp Liner are made of Biolox *forte*, Biolox Delta, or CoCr alloy.

Predicate Devices:
Liners
Comparative information presented in the 510(k) supports the substantial equivalence of the EXp Acetabular Liner with respect to its indications for use, design, materials, and function.

This 510(k) demonstrates the substantial equivalence of the EXp Acetabular Liner to the following predicate devices: Acetabular Liners in the Stelkast Provident Hip System (K935484) and the Stelkast ProForm Hip System (K950827); Biomet RingLoc Acetabular Component with ArCom Polyethylene (K032396 and K970501). Previously cleared polyethylene acetabular liners to which Vitamin E has been added include the Biomet E-Poly (Vitamin E) Acetabular Liners (K050327).

All of these acetabular liners have the same intended use, have the same general design and available sizes, and are made of UHMWPE.

Non-clinical testing was performed on the EXp Acetabular Liner to determine tensile strength, impact strength, compressive strength, small punch strength, thermal properties, free radical concentration, oxidation resistance, swell ratio, hip simulator wear under normal and abrasive conditions, wear particle characterization, rim impingement, liner push-out, lever-out, and torque-out resistance, GCMS analysis of hexane extract post-wear testing, fusion defect characterization, fatigue crack propagation, trans-vinylene index, and biocompatibility (i.e., mutagenicity, irritation, sensitization, and cytotoxicity testing).

The results of the performed tests demonstrate that the EXp Acetabular Liner is substantially equivalent to legally marketed predicate devices.

Femoral Heads
The StelKast Biolox Delta Ceramic Femoral heads are substantially equivalent to previously cleared Biolox Delta Ceramic Femoral Heads: Smith & Nephew (K083762); Biomet (K073102); Zimmer (K071535); and Howmedica Osteonics (K051588). The StelKast Biolox *forte* Ceramic Femoral Heads were approved for use with StelKast femoral stems in P040051. The CoCr Femoral Heads were cleared for use with StelKast femoral stems in K934162.

Testing in support of the ceramic femoral heads includes static burst strength, fatigue, post-fatigue burst strength, pull-off, and rotational stability.

Claims for the EXp Liner

Oxidative Stability and Mechanical Performance of the EXp material

1) EXp is more resistant to oxidation than conventional UHMWPE and its ultimate load, as measured per ASTM F2183, does not decrease during oxidative aging per ASTM F2003. The EXp UHMWPE is a compression molded GUR 1020 blended with Vitamin E, crosslinked with gamma irradiation and terminally sterilized using ethylene oxide. For comparison, a well recognized industry standard material, conventional GUR 1050 material, sterilized using 25kGy in an inert environment was tested in parallel. The EXp UHMWPE demonstrated resistance to oxidation, as measured using ASTM F2102, after aging per ASTM F2003. Specifically, after four weeks of aging per ASTM F2003, the maximum ASTM F2102 oxidation index increased from 0.1 ± 0.02 to 0.2 ± 0.02 for the EXp material and from 0.1 ± 0.04 to 3.8 ± 0.2 for the conventional GUR1050 material.

   Consistent with the oxidation index data, the resulting mechanical performance of the materials, as determined using the ASTM F2183 small punch test, showed that the EXp material retained its mechanical performance while that of the 25kGy GUR 1050 material decreased. Specifically, the ultimate load for the EXp material remained relatively constant, 63.3 ± 8.9 N and 73.1 ± 5.2 N, for the non-aged and 4-week-aged material, respectively. The ultimate load for the conventional material decreased from 71.5 ± 3.0 N for the non-aged material to an embrittled condition in which no small punch sample could be machined. For reference, the ultimate load after two weeks of aging had reduced to 45.7 ± 5.9 N.

   All EXp samples were machined from GUR1020- E, which is blended by percentage weight with Vitamin E, compression molded, crosslinked with gamma irradiation, and subsequently ethylene oxide sterilized. All conventional samples were machined from GUR1050, ram extruded UHMWPE and subsequently gamma sterilized using 25-40 kGy in an inert environment. *Bench testing is not necessarily indicative of clinical performance.*

2) The morphology of the EXp UHMWPE is consistent with conventional UHMWPE. Material samples of both the EXp UHMWPE and 25kGy GUR 1050 material were subjected to freeze fracture analysis. Both materials demonstrated no consolidation defects or voids when imaged at high magnification under scanning electron microscopy.

   All EXp samples were machined from GUR1020- E, which is blended by percentage weight with Vitamin E, compression molded, crosslinked with gamma irradiation, and subsequently ethylene oxide sterilized. All conventional samples were machined from GUR1050, ram extruded UHMWPE and subsequently gamma sterilized using 25-40 kGy in an inert environment. *Bench testing is not necessarily indicative of clinical performance.*

3) The vitamin E blended into the EXp UHMWPE does not elute from the EXp material during hexane extraction or isopropanol (IPA) extraction. Gas chromatography-mass spectrometry (GC-MS) and liquid chromatography –mass spectrometry (LC-MS) analysis of hexane solvent used for extraction of the EXp material confirmed that no Vitamin E was extracted from the material when refluxed at 74°C for 24 hours. GC-MS and LC-MS analysis of IPA solvent used for extraction of the EXp material confirmed

that no Vitamin E was extracted from the material when soaked at room temperature for 18 hours. The GC-MS and LC-MS technique have detection limits of 50-250 ppb and 1000 ppm, respectively.

All EXp samples were machined from GUR1020- E, which is blended by percentage weight with Vitamin E, compression molded, crosslinked with gamma irradiation, and subsequently ethylene oxide sterilized. *Bench testing is not necessarily indicative of clinical performance.*

Oxidative Stability and Mechanical Performance of the EXp Liners

4) EXp remains resistant to oxidation after 5 million cycles of wear testing and artificial aging. Wear testing followed by accelerated aging provides a method to assess the possibility that repeated loading experienced during wear testing may change the distribution or content of the Vitamin E in the EXp material; leaving the material susceptible to oxidation. Testing was conducted per ISO 14242-1 using an AMTI hip simulator with 20g/L bovine serum lubricant to a total cycle count of 5.0 million cycles. All samples were tested in their final sterilized form. Following wear testing, the EXp Liners were aged in an oxidative environment per ASTM F2003 for 4 weeks. The EXp Liners demonstrated a resistance to oxidation, as measured using ASTM F2102. Specifically, the maximum oxidation index increased from 0.1 ± 0.02 for the non-aged EXp material to 0.2 ± 0.02 for the four-week-aged EXp material.

   EXp samples were machined from GUR1020- E, which is blended by percentage weight with Vitamin E, compression molded, crosslinked with gamma irradiation, and subsequently ethylene oxide sterilized. *Bench testing is not necessarily indicative of clinical performance.*

5) The EXp liners experienced no failures as a result of dynamic impingement testing. Dynamic impingement testing, per ASTM F2582, confirmed that artificially aged EXp liners demonstrated a resistance to rim fracture under fatigue loading conditions to 1.0MC. Specifically, three liners were loaded to engage the liner rim with the femoral neck at moments equal to 4.6 Nm (70% of the static peak dislocation moments). All three samples reached run-out equal to 1.0MC and no fractures of the liners were observed throughout testing nor did the locking mechanism fail.

   All EXp samples were machined from GUR1020- E, which is blended by percentage weight with Vitamin E, compression molded, crosslinked with gamma irradiation, and subsequently ethylene oxide sterilized. *Bench testing is not necessarily indicative of clinical performance.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

StelKast, Inc.
% Mr. Donald A. Stevens
Vice Chairman
200 Hidden Valley Road
McMurray, Pennsylvania 15317

MAR 24 2011

Re: K094035
Trade/Device Name: EXp Acetabular Shell Liner
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: OQG, OQH, OQI, LPH, LWJ, JDI, MAY, LZO
Dated: March 15, 2011
Received: March 17, 2011

Dear Mr. Stevens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K094035

Device Name: EXp Acetabular Liner

Indications for Use:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip Arthroplasty.

Cemented and Uncemented Applications

Prescription Use ___YES___ **AND/OR** **Over-The-Counter Use** ___NO___
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K094035