K111981

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OCT 12 2012

SECTION 5: 510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of SMDA and 21CFR § 807.92

Submitted by: Aston® Medical
19, rue Victor Grignard
Zone Industrielle de Montreynaud
42000 Saint-Etienne
France

Prepared By/Contact Person: Catherine Gloster, M.Sc., RAC
Regulatory Consultant
Gloster Biomedical International
577 North Hope Ave
Santa Barbara, CA 93110 - USA
Phone: 805-679-1258
Fax: 805-682-1250
Email: c.gloster@GlosterBiomedical.com

Date Prepared: September 21, 2012

Proprietary Name: TREGOR® Dual Mobility Acetabular System

Common Name: Metal back acetabular cup with dual mobility insert

Classification: Class II, 21 CFR 888.3353 / 888.3358 / 888.3350
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Hip joint metal/polymer semi-constrained cemented prosthesis
LZO / MEH / LPH / JDI

Predicate Devices:

K070278	Plus Orthopedics AG, USA – POLARCUP® Dual Mobility System– cleared 04/16/2007
K072020	Stryker®, Inc. (formerly Howmedica Osteonics Corp.) – Restoration ADM X3® Mobile Bearing™ Hip System – cleared 10/18/2007
K083116	Medacta International, SA. USA – Versafit Cup Double Mobility System – cleared 04/07/2009

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K101336 Biomet Manufacturing Corp., E1® Active Articulation Dual Mobility Hip System – cleared 01/14/2011
K092198 Corin USA – Cormet Cementless Resurfacing Femoral Head
Pre-Medical Device Amendment to Food, Drug and Cosmetic Act of 1976 – Charnley design acetabular cup

Device Description:
The TREGOR® Dual Mobility Acetabular System includes the acetabular components of a total hip prosthesis. Its design is based on the original 1976 Dual Mobility design developed by Prof. Bousquet: it uses two distinct articulating surfaces.
The TREGOR® Dual Mobility Acetabular System is composed of a metal acetabular cup/shell and a dual mobility polyethylene insert. The articulating surfaces are: between the cup and the dual mobility insert, and between the dual mobility insert and the femoral head. The acetabular cup is made of wrought high nitrogen stainless steel (M30NW) for the cemented cup design (TREGOR® Medial Cup) and of Cobalt/Chromium alloy for all other cementless cup designs that are intended for a press-fit application. When used with cement, an acetabular reinforcement accessory with screws may also be used. When used without cement, the cup may include additional fixation aids (screws, pegs, blades) and includes a non-porous double coating. The plasma spray coating is made of pure titanium and hydroxyapatite (Ti/HA). The insert is made of ultra-high-molecular-weight polyethylene (UHMWPE).

There are five configurations of acetabular cups covering a wide range of sizes with dual mobility inserts compatible with 28 mm prosthetic femoral heads made of CrCo or ceramic:

- TREGOR® Standard (6 sizes from 52 to 62 mm outer diameter): Ti/HA coating, cementless and press fit application.
- TREGOR® 3 Blades (6 sizes from 52 to 62 mm outer diameter): Ti/HA coating, cementless and press fit application. Blades provide additional fixation.
- TREGOR® + (7 sizes from 52 to 64 mm outer diameter): Ti/HA coating, cementless and press fit application. Blades and screws provide additional fixation.
- TREGOR® Tripod (7 sizes from 52 to 64 mm outer diameter): Ti/HA coating, cementless and press fit application. Pegs and screw provide additional fixation.
- TREGOR® Medial Cup (5 sizes from 52 to 60 mm outer diameter): for cemented use only. An optional acetabular reinforcement cross is for cemented use only.

The device is single use and provided sterile.

This premarket notification does not include the femoral components. The TREGOR® Dual Mobility Acetabular System is compatible with FDA cleared StelKast femoral components: Provident, Protract and Progeny femoral stems with the femoral heads made of cobalt-chromium and ceramics, listed below. The femoral heads fully cover the morse

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taper of the femoral stem neck and the stems all have a polished, highly polished or electro-polished neck:

- Prosthetic head made of Cobalt-Chromium: 28 mm (StelKast reference SC1151: -5 mm, -3.5 mm, standard and +3.5 mm offset)
- Biolox Delta Femoral head: 28 mm (StelKast reference SC3347, -3.5 mm, standard and +3.5 mm offset)

Indication for Use:

The TREGOR® Dual Mobility Acetabular System is indicated for hip pathologies requiring total hip replacement (THR):

- Non inflammatory or rheumatoid arthritis;
- Osteonecrosis of femoral head;
- Hip deformity affecting its function;
- Non-union head fracture or complex pertrochanteric fracture that are unmanageable using other techniques;
- Revision of previous hip surgery;
- Dislocation risks (e.g., ASA score ≥ 3)

The TREGOR® Dual Mobility Acetabular System hip prosthesis is intended for use in skeletally mature individuals undergoing surgery for rehabilitating hip joints.

Method of fixation:

When used with the TREGOR® Standard acetabular cup with dual Ti/HA coating, the TREGOR® Dual Mobility Acetabular System is for cementless use only and press fit application.

When used with the TREGOR® with Blades acetabular cup with dual Ti/HA coating, the TREGOR® Dual Mobility Acetabular System is for cementless use only and press fit application. The TREGOR® with Blades acetabular cup has blades for additional fixation.

When used with the TREGOR® + acetabular cup with dual Ti/HA coating, the TREGOR® Dual Mobility Acetabular System is for cementless use only and press fit application. The TREGOR® + acetabular cup has blades and screws for additional fixation.

When used with the TREGOR® Tripod acetabular cup with dual Ti/HA coating, the TREGOR® Dual Mobility Acetabular System is for cementless use only and press fit application. The TREGOR® Tripod acetabular cup has pegs and screw for additional fixation.

When used with the TREGOR® Medial Cup acetabular cup, the TREGOR® Dual Mobility Acetabular System is for cemented use only. An optional acetabular reinforcement cross maybe be used with the TREGOR® Medial Cup, also for cemented use only.

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Basis for substantial equivalence:
The TREGOR® Dual Mobility Acetabular System is substantially equivalent to the previously cleared devices: Plus Orthopedics POLARCUP® Dual Mobility System (K070278), Stryker® Restoration™ ADM X3® Mobile Bearing Hip™ System (K072020), Medacta Versafit® Cup Double Mobility (K083116), Biomet E1™ Active Articulation Dual Mobility Hip System (K101336), and the pre-1976 Medical Device Amendment to the Food, Drug and Cosmetic act device called the Charnley acetabular cup. The coating of the TREGOR® Dual Mobility Acetabular System is the same as the coating used on the previously cleared device Cormet Cementless Resurfacing Femoral Head (K092198). The assessment for substantial equivalence is based on similarities in indications for use, materials, dimensions, design, packaging and sterilization processes and results of pre-clinical testing. The subject device does not raise any new issues of safety and effectiveness.

Performance Data:
Pre-clinical performance testing was conducted in accordance with various international standards and FDA guidance documents. The following tests were conducted:

- Dimensional and sizes analysis
- Static test of dual mobility insert dislocation pull-out
- Static test of dual mobility insert dislocation lever out
- Static and fatigue loading testing of the acetabular cup
- Range of motion analysis
- Jump distance analysis
- Holding of cemented cup under flexion and torsion loading
- Axial holding of tripod peg under loading
- Wear of polyethylene of dual mobility insert
- Dual Titanium and Hydroxyapatite coating characterization

All acceptance criteria were met.
Results concluded that the TREGOR® Dual Mobility Acetabular System finished product and its components met all pre-determined specifications and are adequate for their intended use.
Clinical data were not required for this device.

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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

OCT 12 2012

Aston Medical
% Gloster Biomedical International
Ms. Catherine Gloster, M.Sc., RAC
Regulatory Consultant
577 North Hope Avenue
Santa Barbara, California 93110

Re: K111981
Trade/Device Name: TREGOR® Dual Mobility Acetabular System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH, LPH, JDI
Dated: September 21, 2012
Received: September 24, 2012

Dear Ms. Gloster:

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

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

Indication for Use

510(k) K111981

TREGOR® Dual Mobility Acetabular System manufactured by Aston® Medical.

Indications for Use:

The TREGOR® Dual Mobility Acetabular System is indicated for hip pathologies requiring total hip replacement (THR):

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- Revision of previous hip surgery;
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Method of fixation:

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When used with the TREGOR® + acetabular cup with dual Ti/HA coating, the TREGOR® Dual Mobility Acetabular System is for cementless use only and press fit application. The TREGOR® + acetabular cup has blades and screws for additional fixation.

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When used with the TREGOR® Medial Cup acetabular cup, the TREGOR® Dual Mobility Acetabular System is for cemented use only. An optional acetabular

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reinforcement cross maybe be used with the TREGOR® Medial Cup, also for cemented use only.

Prescription Use _X_____	AND/OR	Over-The-Counter Use _____
(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)

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

510(k) Number K111981

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