

**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  
Email: c.gloster@GlosterBiomedical.com

Date Prepared: October 28, 2011

Proprietary Name: DUOCENTRIC® Reversed

Common Name: Reverse shoulder prosthesis

Classification: Class II, 21 CFR 888.3660  
Shoulder joint metal/polymer semi-constrained  
cemented prosthesis  
KWS

Predicate Devices: **K091751** – Depuy Orthopaedic, Inc. USA – Depuy  
Delta Xtend Reverse Shoulder - cleared 7/14/2009  
**K021478** – Depuy Orthopaedic, Inc. USA – Delta  
Shoulder – cleared 11/18/2003  
**K100142** – Tornier, France – Aequalis Reversed  
Shoulder Prosthesis – cleared 5/6/2010  
**K053274** – Zimmer, Inc. USA – Anatomical  
Shoulder™ Inverse/Reverse – cleared 1/25/2006

Device Description: The Duocentric® Reversed shoulder prosthesis is a  
prosthesis that uses the biomechanical concepts of  
reverse shoulder arthroplasty as originally described  
by Paul Grammont.

K103251

The Duocentric® Reversed shoulder prosthesis is composed of a humeral stem, a humeral baseplate, a humeral insert, a glenosphere (Duoglene), and a glenoid baseplate. The humeral insert is made of ultra-high-molecular-weight polyethylene (UHMWPE), while all other components are made of wrought high nitrogen stainless steel M30NW. The humeral stem is intended for cemented use unless coated with hydroxyapatite (HA). The glenoid baseplate is coated with a double coating of pure titanium and hydroxyapatite (Ti/HA), is intended for cementless use, and is fixated with wrought high nitrogen stainless steel screws. The device is provided sterile.

The HA and Ti/HA coatings conform to ASTM standards ASTM F1185, ASTM F1609, and ASTM F1580 and are performed by Medical Coating (Vault-en-Velin, FR) according to their Master File MAF-1633.

Indication for Use:

Implantation of a joint prosthesis is to be considered only when all other surgical options have been carefully examined and found less appropriate.

The Duocentric® Reversed shoulder prosthesis is indicated for use in case of gross rotator cuff deficiency including when it is associated with osteoarthritis, revision of previous arthroplasty or complex fracture of the humerus (3 fragments or more) in an older population (e.g. 65 years of age or older).

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

The humeral stem is intended for use with cement when polished or without cement when coated with Hydroxyapatite. All other components are intended for cementless use only. The glenoid baseplate is intended for cementless application with the addition of three screws for fixation. It is coated with a double layer of pure Titanium and Hydroxyapatite on its posterior side.

K103251

Basis for substantial equivalence:

The Duocentric® Reversed shoulder prosthesis is substantially equivalent to the previously cleared devices: Depuy Delta Xtend Reversed Shoulder (K091751), Depuy Delta Shoulder (K021478), Tornier Aequalis Reverse Shoulder (K100142), and Zimmer Anatomical Reverse/Inverse Shoulder (K053274). This assessment 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 concluded that the Duocentric® Reversed shoulder 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. This product has been commercialized since 2003 in Europe and has shown to be safe and effective as shown by post-market data.



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

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

OCT 28 2011

Re: K103251

Trade/Device Name: Duocentric<sup>®</sup> Reversed shoulder prosthesis: Ashton<sup>®</sup> Medical  
Regulation Number: 21 CFR 888.3660  
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis  
Regulatory Class: Class II  
Product Code: KWS  
Dated: September 30, 2011  
Received: October 3, 2011

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.

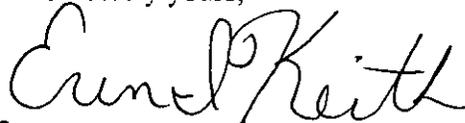
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 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,



*fs* 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): K103251

Duocentric® Reversed shoulder prosthesis: Aston® Medical

### Indications for Use:

Implantation of a joint prosthesis is to be considered only when all other surgical options have been carefully examined and found less appropriate.

The Duocentric® Reversed shoulder prosthesis is indicated for use in case of gross rotator cuff deficiency including when it is associated with osteoarthritis, revision of previous arthroplasty or complex fracture of the humerus (3 fragments or more) in an older population (e.g. 65 years of age or older).

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

The humeral stem is intended for use with cement when polished or without cement when coated with Hydroxyapatite. All other components are intended for cementless use only.

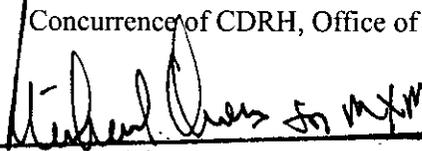
The glenoid baseplate is intended for cementless application with the addition of three screws for fixation. It is coated with a double layer of pure Titanium and Hydroxyapatite on its posterior side.

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)

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

Page 1 of 1