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DEC - 6 2006

DVO
Extremity Solutions
720 E. Winona Ave., Warsaw, IN 46580

510(k) Summary of Safety and Effectiveness

SUMMARY PREPARED:	28 NOVEMBER 2006
510(k) SPONSOR/APPLICANT:	DVO™ Extremity Solutions, LLC 720 E. Winona Ave., Warsaw IN 46580
510(k) PREPARER and CONTACT PERSON:	Dina L. Weissman, J.D. P.O. Box 205, Derby CT 06418 Tel: (203) 736-8631, Email: dina.weissman@sbcglobal.net
TRADE NAME:	Total and Hemi Shoulder System
COMMON NAMES:	Shoulder prosthesis, humeral head
CLASSIFICATION, CLASS and DEVICE PRODUCT CODE:	21 CFR 888.3660 Class II, 87 KWS 21 CFR 888.3690, Class II, 87 HSD
PREDICATE DEVICES:	The DePuy Global shoulder system cleared in: • Total Shoulder, K905786, K914000 • Advantage Shoulder Humeral Stem and Eccentric Head, K992065

DEVICE DESCRIPTION:

This sterile modular total and hemi shoulder system is comprised of a humeral stem, two styles of humeral heads (standard and eccentric) and two styles of glenoids (pegged or keeled). The heads mate on the stems through a locking taper. The heads are highly polished and articulate with the glenoids.

The humeral stems are offered in two lengths: standard (110mm with diameters of 6 to 16mm) or long (200 to 220mm in length with diameters of 8 to 14mm). The stems are fluted, except for the 6mm diameter stem. The stems also have fins with suture holes. The head is available in 15 standard sizes (40 to 56mm in heights of 15, 18 and 21 mm) and 10 eccentric sizes (40 to 56mm in heights of 18mm or 21mm).

Materials include titanium humeral stems, cobalt chrome humeral heads and ultrahigh molecular weight polyethylene glenoids.

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INTENDED USE:

The DVO™ Total and Hemi Shoulder System is intended for use in total or hemi-arthroplasty.

INDICATIONS FOR USE:

The DVO™ Total and Hemi Shoulder System is indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;
2. Fracture/dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory;
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).

Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures;
2. Avascular necrosis of the humeral head.
3. Rotator cuff tear arthropathy.

Humeral stems and glenoids labeled "for cemented use only" are indicated only for use with bone cement. Humeral stems are also indicated for press-fit uncemented use or for use with bone cement.

This is a single use device.

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COMPARISON TO PREDICATES:

The DVO Total and Hemi Shoulder System is similar to the listed predicate devices in intended use for total or hemi shoulder replacement, performance characteristics, materials of construction (titanium alloy, cobalt chrome alloy and UHMWPE), methods of sterilization (gamma irradiation), packaging, manufacturing methods and design. This is evidenced by comparison of technological characteristics, dimensional analysis and nonclinical testing.

Specifically, both the DVO subject devices and the DePuy predicate devices are comprised of a humeral stem and a humeral head mating together with an articulating UHMWPE glenoid. The locking tapers for the head and stem are similar in both the subject and predicate systems.

The stems of both systems are offered in similar lengths (standard and long), with similar diameters. The stems are also similar in being tapered, fluted and having fins with suture holes.

The heads of both systems are of similar size and shape and are offered in standard or eccentric styles. Curvature sizes range from 40mm to 56mm with head heights of 15mm, 18mm and 21mm.

The UHMWPE glenoids of both systems are offer in both pegged and keeled configurations.

The systems also share equal indications for use.

From the standpoint of strength analysis, the subject device is substantially equivalent to the predicate stems because its fatigue load carrying capability exceeds the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 2006

DVO Extremity Solutions, LLC
% Ms. Dina L. Weissman, J.D.
P.O. Box 205
Derby, Connecticut 06418

Re: K060988
Trade/Device Name: DVO™ Total and Hemi Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained, cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD
Dated: November 29, 2006
Received: December 1, 2006

Dear Ms. Weissman:

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.

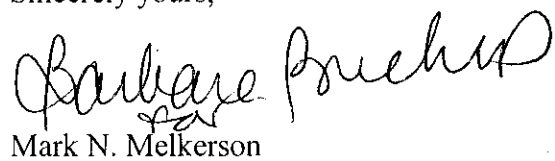
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

K060988

Indications for Use

510(k) Number (if known): K060988

Device Name: DVO™ Total and Hemi Shoulder System

Indications for Use: The DVO™ Total and Hemi Shoulder System is indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;
2. Fracture/dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory;
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Humeral stems and glenoids labeled "for cemented use only" are indicated only for use with bone cement. Humeral stems are indicated for press-fit uncemented use or for use with bone cement.

This is a single use device.

Prescription Use XXXXX (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** No (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler for mxm

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K060988