K093599

NOV 2 4 2010

5. 510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance to the requirements of SDMA 1990 and 21 CFR 807.92.

Date prepared: September 2nd 2010

The assigned 510(k) number is: K0903599

5-1. Applicant:

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6 Rue Nobel, Z.I. de Kernévez
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5-2. Company Contact:

Franck HUNT, General Manager
Tel: (+33) 2.98.55.68.95

5-3. Product :

Trade name: **ARROW® anatomical shoulder system**

Common name: Shoulder prosthesis

Classification: The ARROW® anatomical shoulder system components are included in the following classifications:

- Shoulder joint metal/ polymer semi-constrained cemented prosthesis
  Product code: KWS
  Regulation: 21 CFR 888.3660
  Class: II
- Shoulder joint metal/polymer non-constrained cemented prosthesis
  Product code: KWT
  Regulation: 21 CFR 888.3650
  Class: II
- Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
  Product code: HSD
  Regulation: 21 CFR 888.3690
  Class: II

5-4. Predicate/ Legally Marketed Devices :

Information on devices to which substantial equivalence is claimed:

Manufacturer:	DePuy Orthopaedics, Inc
Device Trade Name:	Global™ Advantage Shoulder
510 (K):	K984541/ K992065

Manufacturer:	Exactech, Inc.
Device Trade Name:	Exactech Equinoxe® Shoulder System
510 (K):	K042021/ K061454

5-5. Device Description:

The ARROW® anatomical shoulder system is a modular shoulder prosthesis, composed of the following elements:

- humeral stems,
- humeral heads (centred or off-centred),
- cemented glenoids.

The ARROW® anatomical shoulder system is intended to be implanted using the dedicated instrumentation supplied by the manufacturer.

5-6. Indications for Use/ Intended Use:

As stated in the Indications for Use section and on the product related labeling (instructions for use and commercial documents):

➢ **Simple humeral prosthesis:**

- Four-part proximal humeral fracture, or dislocation fracture.
- Humeral head necrosis without injury to the glenoid cavity.
- Extensive humeral head cartilage damage without injury to the glenoid cavity
- Centered osteoarthritis with a glenoid cavity not allowing implantation of a glenoid implant.
- Rheumatoid polyarthritis with thin rotator cuff.
- Off-centered osteoarthritis with irreparable cuff, and with maintained active elevation of at least 120°.

➢ **Total anatomical prosthesis (cemented glenoid implant with 4 pegs)**

- Centered glenohumeral osteoarthritis with functional rotator cuff
- Rheumatoid polyarthritis with functional rotator cuff
- Fracture sequela, functional rotator cuff with glenoid injury.

5-7. Comparison of Technological Characteristics:

The ARROW® anatomical shoulder system and the selected predicate devices have the same intended use and substantial similar indications for use and share the following similarities:

- they are made out of the same materials (titanium alloy for the humeral stem, cobalt chromium alloy for the humeral head, polyethylene for the cemented glenoid),
- they are available in similar ranges of sizes,
- they bear design features similarities.

5-8. Performances:

The ARROW® anatomical shoulder system was tested according to ASTM F1738-05, ASTM F1829-98 and ASTM F2028-05 for the glenoid components.

After the testing was completed, it was determined that the ARROW® anatomical shoulder system performances were substantially equivalent to those of the selected predicate devices.

Risks to health have been addressed through the specified materials, processing controls, quality assurance and compliance to the Medical Device Good Manufacturing Practices Regulations.

5-9. Substantial Equivalence:

The substantial equivalence of our products when compared to the selected predicate devices has been established following manufacturers' commercial documents, 510(k) submission's information available on FDA's website as well as conformance to standards in force.
The analysis of these technical data allows us to submit the ARROW® anatomical shoulder system as being substantially equivalent to the already cleared predicate devices selected to a draw a comparison.
All data on predicate devices which has been used to establish substantial equivalence is available in appendix 8.

5-10. Conclusion:

Following the examination of all the above mentioned information, we believe that the ARROW® anatomical shoulder system is substantially equivalent to the selected predicate devices in terms of design, ranges of sizes, materials, intended use, performances, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Fournitures Hospitalieres Industrie
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Regulatory Affairs
Zl de Kernevez
6 rue Nobel
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France

NOV 2 4 2010

Re: K093599
Trade/Device Name: ARROW® anatomical 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, KWT, HSD
Dated: October 25, 2010
Received: October 27, 2010

Dear Ms. Donnard:

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 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

4. Indications for Use

510(k) Number (if known): K093599

NOV 2 4 2010

Device Name: **ARROW® anatomical shoulder system**
This device is composed of the following elements:

- humeral stems,
- humeral heads (centred or off-centred),
- cemented glenoids.

Indications for Use: **The ARROW® anatomical shoulder system,** depending on the components used, is designed for:

Simple humeral prosthesis:

- Fracture dislocation or complex four part fracture of the proximal humerus
- Humeral head necrosis without injury to the glenoid cavity.
- Extensive humeral head cartilage damage without injury to the glenoid cavity
- Centered osteoarthritis with a glenoid cavity not allowing implantation of a glenoid implant.
- Rheumatoid polyarthritis with thin rotator cuff.
- Off-centered osteoarthritis with irreparable cuff, and with maintained active elevation of at least 120°.

Total anatomical prosthesis (cemented glenoid implant with 4 pegs)

- Centered glenohumeral osteoarthritis with functional rotator cuff
- Rheumatoid polyarthritis with functional rotator cuff
- Fracture sequela, functional rotator cuff with glenoid injury.

Prescription Use: __**Yes**__ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page __ of ___

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

510(k) Number K093599