DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

October 29, 2015

Fournitures Hospitalières industrie
Ms. Patricia Donnard
General Manager
6 Rue Nobel, Z.I. de Kernévez
29000 Quimper
France

Re: K150568
Trade/Device Name: ARROW® Humeral stems size 6 and 16
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis.
Regulatory Class: Class II
Product Code: PHX, KWT, HSD
Dated: September 30, 2015
Received: October 5, 2015

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. 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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 -S

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

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K150568

Device Name: **ARROW® Humeral stems size 6 and 16.**
This device is composed of the following elements:
Two stems size 6 and 16. These devices are designed to articulate with ARROW® anatomical shoulder system cleared in K093599 and ARROW® reverse shoulder system cleared in K112193.

Indications for Use: **ARROW® Humeral stems size 6 and 16,** depending on the components used, are 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
- Centred osteoarthritis with a glenoid cavity not allowing implantation of a glenoid implant.
- Rheumatoid polyarthritis with thin rotator cuff.
- Off-centred osteoarthritis with irreparable cuff, and with maintained active elevation of at least 120°.

TOTAL ANATOMICAL PROSTHESIS (CEMENTED GLENOID IMPLANT WITH 4 PEGS):
- Centred glenohumeral osteoarthritis with functional rotator cuff
- Rheumatoid polyarthritis with functional rotator cuff
- Fracture sequela, functional rotator cuff with glenoid injury.

REVERSE PROSTHESIS:
The ARROW Reverse Shoulder Prosthesis is indicated for patients with severe shoulder arthropathy and a grossly deficient rotator cuff or a previously failed shoulder joint replacement with a grossly deficient rotator cuff. A functional deltoid muscle and adequate glenoid bone stock are necessary to use this device. The humeral stem is intended for cemented or cementless application while the metal-back glenoid baseplate is intended for cementless application with the addition of bone screws for fixation.

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: February 27th 2015

The assigned 510(k) number is: K150568

5-1. Applicant:

Fournitures Hospitalières industrie
6 Rue Nobel, Z.I. de Kernévez
29000 QUIMPER - FRANCE
Tel: (+33) 2.98.55.68.95
Fax: (+33) 2.98.53.42.13

5-2. Company Contact:

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

5-3. Product :

Trade name: **ARROW® Humeral stems size 6 and 16.**

Common name: Shoulder prosthesis

Classification: ARROW® Humeral stems size 6 and 16 are included in the following classifications:

-Shoulder joint metal/polymer semi-constrained cemented prosthesis
Product code: PHX
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:

The ARROW® Humeral stems are substantially equivalent to the following legally marketed devices:

Manufacturer:	Fournitures Hospitalières industrie
Device Trade Name:	ARROW® Anatomical Shoulder System
510 (K):	K093599
Manufacturer:	Fournitures Hospitalières industrie
Device Trade Name:	ARROW® Reverse Shoulder System
510 (K):	K112193
Manufacturer:	Exactech, Inc.
Device Trade Name:	Exactech Equinoxe® Shoulder System
510 (K):	K042021 / K061454
Manufacturer:	Exactech, Inc.
Device Trade Name:	Exactech Equinoxe® Reverse Shoulder System
510 (K):	K063569 / K073688

5-5. Device Description:

The ARROW® Humeral stems are composed of two stems size 6 and 16. These devices are designed to articulate with ARROW® anatomical shoulder system cleared in K093599 and ARROW® reverse shoulder system cleared in K112193.

ARROW® Humeral stems size 6 and 16 are intended to be implanted using the dedicated instrumentation supplied by the manufacturer. This instrument set is common for all the configurations of prosthesis (and identical to those for ARROW® anatomical (K093599) and reverse shoulder system (K112193).

5-6. Indications for Use/ Intended Use:

- **Indications for use**

As stated in the Indications for Use section and on the product related labeling (instructions for use and commercial documents):
ARROW® Humeral stems size 6 and 16, depending on the components used, are 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
- Centred osteoarthritis with a glenoid cavity not allowing implantation of a glenoid implant.
- Rheumatoid polyarthritis with thin rotator cuff.
- Off-centred osteoarthritis with irreparable cuff, and with maintained active elevation of at least 120°.

TOTAL ANATOMICAL PROSTHESIS (CEMENTED GLENOID IMPLANT WITH 4 PEGS):
- Centred glenohumeral osteoarthritis with functional rotator cuff
- Rheumatoid polyarthritis with functional rotator cuff
- Fracture sequela, functional rotator cuff with glenoid injury.

REVERSE PROSTHESIS:
The ARROW Reverse Shoulder Prosthesis is indicated for patients with severe shoulder arthropathy and a grossly deficient rotator cuff or a previously failed shoulder joint replacement with a grossly deficient rotator cuff. A functional deltoid muscle and adequate glenoid bone stock are necessary to use this device. The humeral stem is intended for cemented or cementless application while the metal-back glenoid baseplate is intended for cementless application with the addition of bone screws for fixation.

- **Intented use**

All the implants of shoulder prosthesis are used for primary or revision surgeries.
The humeral stem Ø6 is intended for cemented application. The other humeral stems are for cemented or cementless application.

5-7. Comparison of Technological Characteristics:

The ARROW® Humeral stems size 6 and 16 and the above 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),
- they are available in similar ranges of sizes,
- they bear design features similarities.

5-8. Performances:

The ARROW® Humeral stems size 6 and 16 were tested with mechanical tests. After the testing was completed, it was determined that the ARROW® Humeral stems size 6 and 16 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 the commercial documents, 510(k) submission's information as well as conformance to standards in force.
The analysis of these technical data allows us to submit the ARROW® Humeral stems size 6 and 16 as being substantially equivalent to the already cleared predicate devices selected to draw a comparison.

5-10. Conclusion:

Following the examination of all the above mentioned information, we believe that the ARROW® Humeral stems size 6 and 16 are substantially equivalent to the selected predicate devices in terms of intended use, ranges of sizes, materials, performances, safety and effectiveness.