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

April 10, 2017

Fournitures Hospitalieres Industrie
Patricia Donnard
Regulatory Affairs Manager
Z.I. de Kernevez – 6 Rue Nobel
Quimper, 29000 FR

Re: K162068
Trade/Device Name: Arrow Anatomical Porous Glenoid
Regulation Number: 21 CFR 888.3670
Regulation Name: Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBF, KWT, KWS
Dated: March 7, 2017
Received: March 9, 2017

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" (21 CFR 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement on last page*

510(k) Number *(if known)*
**K162068**

Device Name

ARROW® ANATOMICAL POROUS GLENOID

Indications for Use *(Describe)*

THE ARROW ANATOMICAL POROUS GLENOID, DEPENDING ON THE COMPONENTS USED, IS DESIGNED FOR:

- CENTRED GLENOHUMERAL OSTEOARTHRITIS
- RHEUMATOID POLYARTHRITIS
- POST-TRAUMATIC SEQUELA WITH GLENOID INJURY
- FRACTURES OF THE PROXIMAL HUMERUS WITH GLENOID INJURY
- REVISION FOR GLENOID LOOSENING
- GLENOID BONE LOSS, WHERE BONE GRAFT IS NEEDED

A FUNCTIONAL ROTATOR CUFF IS NECESSARY TO USE THIS DEVICE

THE POROUS GLENOID BASE IS INTENDED FOR CEMENTLESS APPLICATION WITH THE ADDITION OF BONE SCREWS FOR FIXATION

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

# 510(k) Summary of safety and effectiveness

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

Date prepared: July 20th 2016

The assigned 510(k) number is: **K162068**

## 1. Applicant

Fournitures Hospitalières industrie
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## 2. Company contact

Philippe VEISTROFFER, General Manager
Tel: (+33) 2.98.55.68.95

## 3. Product

Trade name: ARROW® anatomical porous glenoid

Common name: Shoulder prosthesis

Classification:

Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis.
Product code: MBF
Regulation: 21 CFR 888.3670
Class: II

Shoulder joint metal/polymer non-constrained cemented prosthesis
Product code: KWT
Regulation: 21 CER 888.3650
Class: II

Shoulder joint metal/polymer semi-constrained cemented prosthesis
Product code: KWS
Regulation: 21 CFR 888.3660
Class: II

## 4. Predicate/ Legally marketed devices

The ARROW anatomical porous glenoid, is 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: | Fournitures Hospitalières Industrie |
| Device Trade Name: | ARROW Reverse Shoulder long keel and short keel glenoid base |
| 510 (K): | K142778 |
| Manufacturer: | Biomet Orthopedics |
| Device Trade Name: | Bio-Modular Shoulder System |
| 510 (K): | K030710 |

## 5. Device description

The ARROW anatomical porous glenoid consists of a glenoid insert and a porous glenoid base. The porous glenoid base is used with bone screws for fixation (cleared in K112193).
The glenoid inserts and the porous glenoid bases are used in total anatomical prosthesis and are designed to articulate with the ARROW anatomical shoulder system (cleared in K093599).

The ARROW anatomical porous glenoid is intended to be implanted using the dedicated instrumentation supplied by the manufacturer. This instrument set is common for all the configurations of prosthesis namely: simple humeral prosthesis, total anatomical prosthesis (cemented glenoid implant with 4 pegs), total anatomical prosthesis (porous glenoid implant), pending, and reverse prosthesis.

## 6. Indications for use / Intended use

- Indications for use

TOTAL ANATOMICAL PROSTHESIS (POROUS GLENOID IMPLANT)

- Centred glenohumeral osteoarthritis
- Rheumatoid polyarthritis
- Post-traumatic sequela with glenoid injury
- Fractures of the proximal humerus with glenoid injury
- Revision for glenoid loosening
- Glenoid bone loss, where bone graft is needed

A functional rotator cuff is necessary to use this device
The porous glenoid base is intended for cementless application with the addition of bone screws for fixation.

The ARROW anatomical porous glenoid is a part of the full ARROW shoulder system, which includes other prosthesis configurations with other indications, as below:

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.

- Intended use

All the implants of shoulder prosthesis are used for primary or revision surgeries.
The glenoid base is intended for cementless application with the addition of cortical or cancellous bone screws. The porous glenoid base must be used only for a total anatomical prosthesis.

## 7. Comparison of technological characteristics

The ARROW anatomical porous glenoid 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 for the porous glenoid base and polyethylene for the glenoid insert),
- they are available in similar ranges of sizes,
- they bear design features similarities.

## 8. Performances

The ARROW anatomical porous glenoid was tested according to the ASTM F 1829 and ASTM F 2028 standards. After the tests were completed, it was determined that the ARROW anatomical porous glenoid 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. Testing has been performed to establish product non-pyrogenicity.

## 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 anatomical porous glenoid, as being substantially equivalent to the already cleared predicate devices selected to draw a comparison.

## 10. Conclusion

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