DePuy lnc.
Megan Bernier
Regulatory Affairs Specialist
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

April 2, 2021

Re: K203230
Trade/Device Name: Global Shoulder and Delta CTA systems
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, MBF, PHX
Dated: February 19, 2021
Received: February 22, 2021

Dear Megan Bernier:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Michael Owens
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203230

Device Name
Trade Name: GLOBAL ADVANTAGE

Indications for Use *(Describe)*
The DePuy GLOBAL ADVANTAGE Shoulder Systems

The DePuy GLOBAL ADVANTAGE Shoulder Systems is indicated for use in total or hemi-shoulder replacement for the treatment of:

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).

The DePuy GLOBAL ADVANTAGE Shoulder System is also indicated for hemi-shoulder replacement for the treatment of:

1. Ununited humeral head fractures;
2. Avascular necrosis of the humeral head.

GLOBAL ADVANTAGE CTA Humeral Heads

The DePuy GLOBAL ADVANTAGE CTA Humeral Heads are indicated only for hemi-shoulder replacement in patients with rotator cuff tears.

The DePuy GLOBAL ADVANTAGE CTA Humeral Heads can be used with the GLOBAL FX and GLOBAL ADVANTAGE Humeral Stems in hemi-shoulder replacement in patients with rotator cuff tears.

GLOBAL ADVANTAGE Shoulder Systems Fixation Methods

The DePuy GLOBAL ADVANTAGE Systems are indicated for the following fixation methods:
POROCOAT™ Porous-Coated Components - Porocoat porous-coated humeral stem prostheses are indicated for cemented or uncemented use with fixation provided by biological tissue ingrowth into the porous coating.
Cemented Components - Humeral Stem and Glenoid components labeled "For cemented use only" are indicated only for use with bone cement.
Press-fit or Cemented Components - Humeral stem prostheses without porous coating and labeled "For press-fit or cemented use only" are indicated for press-fit uncemented use or for use with bone cement.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203230

Device Name
Trade Name: GLOBAL FX

Indications for Use *(Describe)*

The DePuy GLOBAL FX Shoulder System is indicated only for hemi-shoulder replacement for the treatment of:

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);
4. Ununited humeral head fractures;
5. Avascular necrosis of the humeral head.

GLOBAL FX Shoulder Systems Fixation Methods

The DePuy GLOBAL FX Shoulder System is indicated for the following fixation methods:

- POROCOAT™ Porous-Coated Components - Porocoat porous-coated humeral stem prostheses are indicated for cemented or uncemented use with fixation provided by biological tissue ingrowth into the porous coating.
- Cemented Components - Humeral Stem and Glenoid components labeled "For cemented use only" are indicated only for use with bone cement.
- Press-fit or Cemented Components - Humeral stem prostheses without porous coating and labeled "For press-fit or cemented use only" are indicated for press-fit uncemented use or for use with bone cement.

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)

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See PRA Statement below.

510(k) Number *(if known)*

K203230

Device Name
Trade Name: GLOBAL™ CAP

Indications for Use *(Describe)*

GLOBAL™ CAP

The DePuy GLOBAL™ CAP Resurfacing Shoulder Humeral Heads are intended as a total or hemi-shoulder replacement in patients where the humeral head and neck are of sufficient bone stock and the rotator cuff is intact or reconstructable. This device is designed to increase shoulder mobility by: reducing pain; restoring alignment; restoring flexion and extension movement; and resisting dislocation.

The DePuy GLOBAL™ CAP Resurfacing Shoulder Humeral Heads are indicated for use as a replacement of shoulder joints disabled by rheumatoid arthritis with pain, non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis), deformity and/or limited motion, fractures of the humeral head and traumatic arthritis.

The DePuy GLOBAL™ CAP Resurfacing Shoulder Humeral Heads are intended for uncemented use only.

GLOBAL™ CAP CTA™

The DePuy GLOBAL ™ CAP CTA Resurfacing Shoulder is indicated only for hemi-shoulder replacement in patients with rotator cuff tears and arthritis. Specific indications include:

1. Rotator cuff tear arthropathy.
2. Difficult clinical management problems where other methods of treatment may not be suitable or may be inadequate.

The DePuy GLOBAL ™CAP CTA Resurfacing Shoulder Humeral Heads are intended for uncemented use only.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203230

Device Name
Trade Name: Global APG

Indications for Use *(Describe)*

The Glenoid is intended for use in total shoulder replacement surgery for patients suffering from:

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 communited, 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).

Glenoid components are intended for cemented use only.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203230

Device Name
Trade Name: GLOBAL AP Shoulder System

Indications for Use *(Describe)*
The DePuy GLOBAL AP Shoulder System

The DePuy GLOBAL AP Shoulder System is indicated for use in total or hemi-shoulder replacement for the treatment of:

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).

The DePuy GLOBAL AP Shoulder Systems is also indicated for hemi-shoulder replacement for the treatment of:

1. Ununited humeral head fractures;
2. Avascular necrosis of the humeral head.

GLOBAL AP™ CTA Humeral Heads

The DePuy GLOBAL AP CTA Humeral Heads are indicated only for hemi-shoulder replacement in patients with rotator cuff tears.

The GLOBAL AP CTA Humeral Head can be used with the GLOBAL AP Humeral Stem in hemi-shoulder replacement in patients with rotator cuff tears.

GLOBAL AP™ Shoulder Systems Fixation Methods.

The DePuy GLOBAL AP Shoulder Systems are indicated for the following fixation methods:

POROCOAT™ Porous-Coated Components - Porocoat porous-coated humeral stem prostheses are indicated for cemented or uncemented use with fixation provided by biological tissue ingrowth into the porous coating.
Cemented Components - Humeral Stem and Glenoid components labeled "For cemented use only" are indicated only for use with bone cement.
Press-fit or Cemented Components - Humeral stem prostheses without porous coating and labeled "For press-fit or cemented use only" are indicated for press-fit uncemented use or for use with bone cement.

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)

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Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203230

Device Name
Trade Name: Global StepTech

Indications for Use *(Describe)*
The StepTech Anchor Peg Glenoid is intended for use in total shoulder replacement surgery for patients suffering from:

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 communited, 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).

Glenoid components are intended for cemented use only.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203230

Device Name
Trade Name: Global Shoulder

Indications for Use *(Describe)*
The Glenoid is intended for use in total shoulder replacement surgery for patients suffering from:
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 surfaces are severely communited, 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).

Glenoid components are intended for cemented use only.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203230

Device Name
Trade Name: DELTA CTA™

Indications for Use *(Describe)*
The DELTA CTA™ Reverse Shoulder Prosthesis is indicated for use in:

1. Grossly rotator cuff deficient joint with severe arthropathy or a previous failed joint replacement with a grossly rotator cuff deficient joint.
2. The DELTA CTA™ hemi-shoulder replacement is also indicated for hemi-arthroplasty if the glenoid is fractured intraoperatively or for revision surgery in cases with insufficient glenoid bone stock.
3. 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.

For US use only: All components are intended for cemented use only

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)

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DePuy Synthes

Traditional 510(k) Notification
Global Shoulder and Delta CTA MRI

510(k) SUMMARY

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

I. SUBMITTER

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Contact Person:	Megan Bernier
Email:	mbernie1@its.jnj.com
Phone/Fax:	(651) 325-1178 ; FAX (612) 435-2372
Mobile:	(651) 325-1178

Date Prepared:	March 30, 2021
Prepared By:	Megan Bernier
Trade/Device Name:	Global Shoulder and Delta CTA systems
Regulation Name:	Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Product Codes:	KWS:888.3660 KWT:888.3650 HSD:888.3690 MBF:888.3670 PHX:888.3660

II. DEVICE

Table 5- 1 Global Shoulder - GLOBAL ADVANTAGE

Trade Name: GLOBAL ADVANTAGE				
Device Name:	GlobalTM Shoulder -Global™ Fx Humeral Stem -+Global™ Advantage® Humeral Head	Global Advantage Shoulder, Global Advantage Humeral Stem, Global Advantage Eccentric Head	Global Advantage Extended Humeral Head	Global Advantage Humeral Stem with Porocoat
Common Name:	Shoulder prosthesis, humeral head	Shoulder prosthesis, humeral head	Prosthesis, Shoulder, Humeral Head	Prosthesis, Shoulder, Humeral Head
Classification Name:	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer, Uncemented
Product Code:	KWT	KWS	HSD	MBF
Regulatory Class:	Class II	Class II	Class II	Class II
Regulation Number:	888.3670	888.3660	888.3690	888.3670
510 (k) Review Panel:	Orthopedic	Orthopedic	Orthopedic	Orthopedic

Table 5- 2 Global Shoulder - GLOBAL FX

Trade Name: Global FX		
Device Name:	Global FX Porous-coated humeral STEM	Global FX Porous-coated humeral STEM
Common Name:	Shoulder prosthesis, humeral head	Shoulder prosthesis, humeral head
Classification Name:	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented
Product Code:	KWT	MBF
Regulatory Class:	Class II	Class II
Regulation Number:	888.3670	888.3670
510 (k) Review Panel:	Orthopedic	Orthopedic

Table 5- 3 Global Shoulder - GLOBAL™ CAP

Trade Name: Global CAP		
Device Name:	DePuy Global CAP™ HA Resurfacing Shoulder Humeral	DePuy Global CAP CTA Resurfacing Shoulder
Common Name:	Prosthesis, Shoulder, Humeral Head	Prosthesis, Shoulder, Humeral Head
Classification Name:	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented
Product Code:	HSD	HSD
Regulatory Class:	Class II	Class II
Regulation Number:	888.3690	888.3690
510 (k) Review Panel:	Orthopedic	Orthopedic

Table 5- 4 Global Shoulder - Global APG

Trade Name: Global APG		
Device Name:	DePuy Global Shoulder Glenoid	DePuy Global Shoulder Crosslink Glenoid DePuy Orthopaedica. Inc.
Common Name:	Shoulder Prosthesis	Shoulder Prosthesis
Classification Name:	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented
Product Code:	KWS	KWS
Regulatory Class:	Class II	Class II
Regulation Number:	888.3660	888.3660
510 (k) Review Panel:	Orthopedic	Orthopedic

Table 5- 5 Global Shoulder - GLOBAL AP

Trade Name: Global AP			
Device Name:	DePuy Global AP™ Shoulder System	Global AP Porous Coated Humeral Steme	DePuy Global AP CTA Humeral Head
Common Name:	Shoulder Prosthesis	Shoulder Prosthesis	Prosthesis, Shoulder, Humeral Head
Classification Name:	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented
Product Code:	KWS	KWS	HSD
Regulatory Class:	Class II	Class II	Class II
Regulation Number:	888.3660	888.3660	888.3690
510 (k) Review Panel:	Orthopedic	Orthopedic	Orthopedic

Table 5- 6 Global Shoulder – Global StepTech

Trade Name: GLOBAL® STEPTECH®	
Device Name:	Global Shoulder StepTech Anchor Peg Glenoid
Common Name:	Shoulder Prosthesis
Classification Name:	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented
Product Code:	KWS
Regulatory Class:	Class II
Regulation Number:	888.3660
510(k) Review Panel:	Orthopedic

Table 5- 7 Global Shoulder - Global Shoulder

Trade Name: GLOBAL® SHOULDER		
Device Name:	Device Name Global™ Total Shoulder W/DuPont Enhanced UHMWPE	DePuy Global Shoulder Crosslink Glenoid
Common Name:	Shoulder Prosthesis	Shoulder Prosthesis
Classification Name:	Prosthesis, Shoulder, Non-Constrained, Metal/polymer Cemented	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented
Product Code:	KWT	KWS
Regulatory Class:	Class II	Class II
Regulation Number:	888.3650	888.3660
510 (k) Review Panel:	Orthopedic	Orthopedic

Table 5- 8 DELTA CTA™

Trade Name: DELTA CTA				
Device Name:	Delta Shoulder	Delta Humeral Cups	Delta Reverse Shoulder System Humeral Head	DePuy CTA Reverse Shoulder System
Common Name:	Shoulder Prosthesis	Shoulder Prosthesis	Shoulder Prosthesis	Shoulder Prosthesis
Classification Name:	Shoulder Prosthesis, Reverse Configuration	Shoulder Prosthesis, Reverse Configuration	Shoulder Prosthesis, Reverse Configuration	Shoulder Prosthesis, Reverse Configuration
Product Code:	PHX	PHX	PHX	PHX
Regulatory Class:	Class II	Class II	Class II	Class II
Regulation Number:	888.3660	888.3660	888.3660	888.3660
510 (k) Review Panel:	Orthopedic	Orthopedic	Orthopedic	Orthopedic

III. PREDICATE DEVICE(S)

Table 5- 9 Predicate Devices: Global Shoulder - GLOBAL ADVANTAGE

Trade Name: GLOBAL ADVANTAGE®				
	K984541	**K992065**	**K000575**	**K011047**
Device Name:	Global™ Shoulder -Global™ Fx Humeral Stem -+Global™ Advantage® Humeral Head	Global Advantage Shoulder, Global Advantage Humeral Stem, Global Advantage Eccentric Head	Global Advantage Extended Humeral Head	Global Advantage Humeral Stem with Porocoat
Common Name:	Shoulder prosthesis, humeral head	Shoulder prosthesis, humeral head	Prosthesis, Shoulder, Humeral Head	Prosthesis, Shoulder, Humeral Head
Classification Name:	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer, Uncemented
Product Code:	KWT	KWS	HSD	MBF
Regulatory Class:	Class II	Class II	Class II	Class II
Regulation Number:	888.3670	888.3660	888.3690	888.3670

Table 5- 10 Predicate Devices: Global Shoulder - GLOBAL FX

Trade Name: Global FX		
	K984541	**K011099**
Device Name:	Global FX Porous-coated humeral STEM	Global FX Porous-coated humeral STEM
Common Name:	Shoulder prosthesis, humeral head	Shoulder prosthesis, humeral head
Classification Name:	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented
Product Code:	KWT	MBF
Regulatory Class:	Class II	Class II
Regulation Number:	888.3670	888.3670

Table 5- 11 Predicate Devices: Global Shoulder - GLOBAL™ CAP

Trade Name: Global CAP		
	K033516	**K080990**
Device Name:	DePuy Global CAP™ HA Resurfacing Shoulder Humeral	DePuy Global CAP CTA Resurfacing Shoulder
Common Name:	Prosthesis, Shoulder, Humeral Head	Prosthesis, Shoulder, Humeral Head
Classification Name:	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented
Product Code:	HSD	HSD
Regulatory Class:	Class II	Class II
Regulation Number:	888.3690	888.3690

Table 5- 12 Predicate Devices: Global Shoulder - Global APG

Trade Name: Global APG		
	K981487	**K052472**
Device Name:	DePuy Global Shoulder Glenoid	DePuy Global Shoulder Crosslink Glenoid DePuy Orthopaedica. Inc.
Common Name:	Shoulder Prosthesis	Shoulder Prosthesis
Classification Name:	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented
Product Code:	KWS	KWS
Regulatory Class:	Class II	Class II
Regulation Number:	888.3660	888.3660

Table 5- 13 Predicate Devices: Global Shoulder - GLOBAL AP

Trade Name: Global AP			
	K060874	**K063652**	**K082715**
Device Name:	DePuy Global AP™ Shoulder System	Global AP Porous Coated Humeral Stem	DePuy Global AP CTA Humeral Head
Common Name:	Shoulder Prosthesis	Shoulder Prosthesis	Prosthesis, Shoulder, Humeral Head
Classification Name:	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented
Product Code:	KWS	KWS	HSD
Regulatory Class:	Class II	Class II	Class II
Regulation Number:	888.3660	888.3660	888.3690

Table 5- 14 Predicate Devices: Global Shoulder – Global StepTech

Trade Name: GLOBAL® STEPTECH®	
	K092122
Device Name:	Global Shoulder StepTech Anchor Peg Glenoid
Common Name:	Shoulder Prosthesis
Classification Name:	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented
Product Code:	KWS
Regulatory Class:	Class II
Regulation Number:	888.3660

Table 5- 15 Predicate Devices: Global Shoulder - Global Shoulder

Trade Name: GLOBAL® SHOULDER		
	K914000; K905786	**K052472**
Device Name:	Device Name Global™ Total Shoulder W/DuPont Enhanced UHMWPE	DePuy Global Shoulder Crosslink Glenoid
Common Name:	Shoulder Prosthesis	Shoulder Prosthesis
Classification Name:	Prosthesis, Shoulder, Non-Constrained, Metal/polymer Cemented	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented
Product Code:	KWT	KWS
Regulatory Class:	Class II	Class II
Regulation Number:	888.3650	888.3660

Table 5- 16 Predicate Devices: DELTA CTA™

Trade Name: DELTA CTA; IFU: W90926 and W90916				
	K021478	**K050315**	**K062116**	**K122442**
Device Name:	Delta Shoulder	Delta Humeral Cups	Delta Reverse Shoulder System Humeral Head	DePuy CTA Reverse Shoulder System
Common Name:	Shoulder Prosthesis	Shoulder Prosthesis	Shoulder Prosthesis	Shoulder Prosthesis
Classification Name:	Shoulder Prosthesis, Reverse Configuration	Shoulder Prosthesis, Reverse Configuration	Shoulder Prosthesis, Reverse Configuration	Shoulder Prosthesis, Reverse Configuration
Product Code:	PHX	PHX	PHX	PHX
Regulatory Class:	Class II	Class II	Class II	Class II
Regulation Number:	888.3660	888.3660	888.3660	888.3660

IV. DEVICE DESCRIPTION

The Global Shoulder System is comprised of multiple brands (Global Advantage, Global FX, Global AP, Global CAP, Global APG and Global Steptech), each comprised of different components (humeral stems, humeral heads and glenoids) intended for hemi- and/or total-shoulder arthroplasty.

The DELTA CTA System is comprised of components intended for reverse shoulder arthroplasty.

V. INDICATIONS FOR USE

Global Shoulder – GLOBAL ADVANTAGE

The DePuy GLOBAL ADVANTAGE Shoulder Systems

The DePuy GLOBAL ADVANTAGE Shoulder Systems is indicated for use in total or hemi-shoulder replacement for the treatment of:
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).

The DePuy GLOBAL ADVANTAGE Shoulder System is also indicated for hemi-shoulder replacement for the treatment of:
1. Ununited humeral head fractures;
2. Avascular necrosis of the humeral head.

GLOBAL ADVANTAGE CTA Humeral Heads

The DePuy GLOBAL ADVANTAGE CTA Humeral Heads are indicated only for hemi-shoulder replacement in patients with rotator cuff tears.

The DePuy GLOBAL ADVANTAGE CTA Humeral Heads can be used with the GLOBAL FX and GLOBAL ADVANTAGE Humeral Stems in hemi-shoulder replacement in patients with rotator cuff tears.

GLOBAL ADVANTAGE Shoulder Systems Fixation Methods

The DePuy GLOBAL ADVANTAGE Systems are indicated for the following fixation methods:

- POROCOAT™ Porous-Coated Components - Porocoat porous-coated humeral stem prostheses are indicated for cemented or uncemented use with fixation provided by biological tissue ingrowth into the porous coating.

- Cemented Components - Humeral Stem and Glenoid components labeled "For cemented use only" are indicated only for use with bone cement.
- Press-fit or Cemented Components - Humeral stem prostheses without porous coating and labeled "For press-fit or cemented use only" are indicated for press-fit uncemented use or for use with bone cement.

Global Shoulder – GLOBAL FX

The DePuy GLOBAL FX Shoulder System is indicated only for hemi-shoulder replacement for the treatment of:

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);
4. Ununited humeral head fractures;
5. Avascular necrosis of the humeral head.

GLOBAL FX Shoulder Systems Fixation Methods

The DePuy GLOBAL FX Shoulder Systems are indicated for the following fixation methods:

- POROCOAT™ Porous-Coated Components - Porocoat porous-coated humeral stem prostheses are indicated for cemented or uncemented use with fixation provided by biological tissue ingrowth into the porous coating.
- Cemented Components - Humeral Stem and Glenoid components labeled "For cemented use only" are indicated only for use with bone cement.
- Press-fit or Cemented Components - Humeral stem prostheses without porous coating and labeled "For press-fit or cemented use only" are indicated for press-fit uncemented use or for use with bone cement.

Global Shoulder – GLOBAL™ CAP

GLOBAL™ CAP

The DePuy GLOBAL™ CAP Resurfacing Shoulder Humeral Heads are intended as a total or hemi-shoulder replacement in patients where the humeral head and neck are of sufficient bone stock and the rotator cuff is intact or reconstructable. This device is designed to increase shoulder mobility by: reducing pain; restoring alignment; restoring flexion and extension movement; and resisting dislocation.

The DePuy GLOBAL™ CAP Resurfacing Shoulder Humeral Heads are indicated for use as a replacement of shoulder joints disabled by rheumatoid arthritis with pain, non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis), deformity and/or limited motion, fractures of the humeral head and traumatic arthritis.

The DePuy GLOBAL™ CAP Resurfacing Shoulder Humeral Heads are intended for uncemented use only.

GLOBAL™ CAP CTA™

The DePuy GLOBAL™ CAP CTA Resurfacing Shoulder is indicated only for hemi-shoulder replacement in patients with rotator cuff tears and arthritis. Specific indications include:

1. Rotator cuff tear arthropathy.

2. Difficult clinical management problems where other methods of treatment may not be suitable or may be inadequate.

The DePuy GLOBAL™ CAP CTA Resurfacing Shoulder Humeral Heads are intended for uncemented use only.

Global Shoulder – Global APG

The Glenoid is intended for use in total shoulder replacement surgery for patients suffering from:

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 communited, 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).

Glenoid components are intended for cemented use only.

Global Shoulder – GLOBAL AP Shoulder System

The DePuy GLOBAL AP Shoulder System

The DePuy GLOBAL AP Shoulder System is indicated for use in total or hemi-shoulder replacement for the treatment of:

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).

The DePuy GLOBAL AP Shoulder Systems is also indicated for hemi-shoulder replacement for the treatment of:

1. Ununited humeral head fractures;

2. Avascular necrosis of the humeral head.

GLOBAL AP™ CTA Humeral Heads

The DePuy GLOBAL AP CTA Humeral Heads are indicated only for hemi-shoulder replacement in patients with rotator cuff tears.

The GLOBAL AP CTA Humeral Head can be used with the GLOBAL AP Humeral Stem in hemi-shoulder replacement in patients with rotator cuff tears.

GLOBAL AP™ Shoulder Systems Fixation Methods.

The DePuy GLOBAL AP Shoulder Systems are indicated for the following fixation methods:

- POROCOAT™ Porous-Coated Components - Porocoat porous-coated humeral stem prostheses are indicated for cemented or uncemented use with fixation provided by biological tissue ingrowth into the porous coating.
- Cemented Components - Humeral Stem and Glenoid components labeled "For cemented use only" are indicated only for use with bone cement.

- Press-fit or Cemented Components - Humeral stem prostheses without porous coating and labeled "For press-fit or cemented use only" are indicated for press-fit uncemented use or for use with bone cement.

Global Shoulder – Global StepTech

The StepTech Anchor Peg Glenoid is intended for use in total shoulder replacement surgery for patients suffering from:

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 communited, 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).

Glenoid components are intended for cemented use only.

Global Shoulder – Global Shoulder

The Glenoid is intended for use in total shoulder replacement surgery for patients suffering from:

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 surfaces are severely communited, 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).

Glenoid components are intended for cemented use only.

Global Shoulder – DELTA CTA™

The DELTA CTA™ Reverse Shoulder Prosthesis is indicated for use in:

1. Grossly rotator cuff deficient joint with severe arthropathy or a previous failed joint replacement with a grossly rotator cuff deficient joint.

2. The DELTA CTA™ hemi-shoulder replacement is also indicated for hemi-arthroplasty if the glenoid is fractured intraoperatively or for revision surgery in cases with insufficient glenoid bone stock.

3. 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.

For US use only: All components are intended for cemented use only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject devices maintain the design characteristics of the predicate devices. Intended use of the subject devices remains the same as the predicate devices. The subject devices are provided with additional labeling language regarding magnetic resonance (MR) compatibility when compared to the predicate devices.

VII. MATERIALS

The subject device materials remain identical to the predicate device materials.

VIII. PERFORMANCE DATA

Non-clinical testing was conducted with the following standards:

- ASTM F2213 *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*
- ASTM F2052 *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*
- ASTM F2119 *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants*
- ASTM F2182 *Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging*

Results demonstrated compatibility conditions of the subject devices in the MR environment.

IX. CONCLUSION

Evaluation of subject device intended use and technological characteristics demonstrates substantial equivalence with the predicate devices. Performance data supports the addition of magnetic resonance compatibility information to subject device labeling.