2.0 510(k) Summary

I. Submitter

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Date Prepared: July 6, 2018

II. Device

Device Proprietary Name:	Glenoid Polyaxial Non-locking Screw
Common or Usual Name:	Screw for Shoulder Prosthesis
Classification Name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Primary Product Code:	PHX, KWS, HSD and MBF
Regulation Number:	21 CFR 888.3660, 21 CFR 888.3690, and 21 CFR 888.3670
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- Glenoid Polyaxial Locking Screw (Medacta Shoulder Reverse System), K170452, Medacta International SA;
- Delta Xtend™ Reverse Shoulder System, K062250 and K071379, DePuy Orthopaedics, Inc;
- SMR™ Modular Shoulder Replacement System, K100858, Lima; and
- AEQUALIS™ REVERSED II Shoulder Prosthesis, K112144, Wright Medical - Tornier.

IV. Device Description

The Glenoid Polyaxial Non-locking Screws are line extensions to the Medacta Shoulder Reverse System (K170452) and the Threaded Glenoid Baseplate (K171058); and provide compatibility with Short Humeral Stem (K180089).

The Glenoid Polyaxial Non-locking Screws implants subject of this submission are comprised of the following products:

- Glenoid Polyaxial non-locking screw, 10 sizes: from L14 mm to L50 mm with 4mm increment.

The Glenoid Polyaxial Non-locking Screws implants are part of the Medacta Shoulder Reverse System. The Medacta Shoulder Reverse System consists of the following components:

- Humeral Diaphysis - Cemented;
- Humeral Diaphysis - Cementless;
- Humeral Reverse Metaphysis;
- Humeral Reverse HC Liner (also referred to as PE Liner);
- Glenoid Baseplate - Pegged;
- Glenoid Baseplate - Threaded;
- Glenoidsphere;
- Glenoid Polyaxial Locking Screw (predicate item);
- Glenoid Polyaxial Non-Locking Screw (subject item);
- Reverse Metaphysis Screw; and
- Glenoidsphere Screw.

The Glenoid Baseplate (pegged version and threaded version) is intended to be fixed on the glenoid bone by means of a central pressfit and with the help of Glenoid Polyaxial Screws. The purpose of this submission is to gain clearance for the new Medacta Glenoid Polyaxial Non-Locking Screws, thus providing to surgeons an alternative to Glenoid Polyaxial Locking Screws for the Glenoid Baseplate fixation process.

The Glenoid Polyaxial Non-Locking Screws are made of Ti alloy (Ti-6Al-4V), enhanced with Type-II anodization, according to *ISO 5832-3:1996 Implants For Surgery - Metallic Materials - Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy*.

The Glenoid Polyaxial Non-Locking Screws are similar to the predicate devices Medacta Glenoid Polyaxial Locking Screw (K170452), DePuy Delta Xtend™ Reverse Shoulder System (K062250 and K071379), Lima SMR™ Modular Shoulder Replacement System (K100858) and Tornier AEQUALIS™ REVERSED II Shoulder Prosthesis (K112144).

V. Indications for Use

The Reverse Shoulder Prosthesis is indicated for treatment of humeral fractures and for primary or revision total shoulder replacement in patients with a grossly rotator cuff deficient shoulder joint with severe arthroplasty or a previously failed joint replacement with a grossly rotator cuff deficient shoulder joint.

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.

The glenoid baseplate is intended for cementless application with the addition of screws for fixation.

VI. Comparison of Technological Characteristics

The Glenoid Polyaxial Non-Locking Screws and the predicate devices share the following characteristics:

- indications for use;
- head design (with exception of Medacta Locking Screw predicate, K170452);
- thread design;
- ROM;
- material of construction;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The Glenoid Polyaxial Non-Locking Screws are technologically different from the predicate devices as follows:

- sizes and lengths.

The subject Glenoid Polyaxial Non-Locking Screws have the same technological characteristics of the Medacta predicate device Glenoid Polyaxial Locking Screws (K170452) with the only exception of the Non-Locking mechanism, feature shared with the other predicates: the Non-Locking screws possess a cylindrical shaped head which allows for the insertion and placement of the implant into the dedicated seat of the baseplate, compressing it on the glenoid vault; on the other hand, the Locking screws own a "petal shaped" head which can also expand in order to lock its position into the baseplate.

The subject Glenoid Polyaxial Non-Locking Screws provide a wider range of lengths if compared to predicate devices and these length options do not represent worst cases because the length of the screws does not have any influence on the mechanical properties (torque resistance and pull-out strength).

Biocompatibility testing conducted on the predicate devices for the same or similar materials supports the biological safety of the Glenoid Polyaxial Non-Locking Screws. Subject and predicate devices are manufactured from the following material: Titanium Alloy (Ti-6Al-4V) *ISO 5832-3:1996 Implants For Surgery - Metallic Materials - Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy*.

This material has an extensive amount of biocompatibility data that has been provided in the listed predicate devices 510(k) submissions Medacta Glenoid Polyaxial Locking Screw (K170452), DePuy Delta Xtend™ (K062250 and K071379), Lima SMR™ Modular Shoulder Replacement System (K100858) and Wright Medical - Tornier AEQUALIS™ REVERSED II Shoulder Prosthesis (K112144).

VII. Performance Data

Testing was conducted according to written protocols with acceptance criteria that were based on standards. The following mechanical studies were performed in support of a substantial equivalence determination:

Non-Clinical Studies:

- Characterization Tests
  - Design Validation Report.
- Performance Tests
  - Micromotions Assessment In Reverse Configuration: ASTM F2028-14: Standards Test Methods For Dynamic Evaluation of Glenoid Loosening Or Disassociation Prostheses;
  - Static Fatigue Testing: ASTM F543-13: Standard Specification And Test Methods For Metallic Medical Bone Screws; and
  - Pull-Out Test: ASTM F543-17: Standard Specification and Test Methods for Metallic Medical Bone Screws.
- Pyrogenicity
  - Bacterial Endotoxin Test (LAL test) was conducted according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>) and pyrogen test according to USP chapter <151> for pyrogenicity determination; and
  - the subject devices are not labeled as non-pyrogenic or pyrogen free.

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

Based on the above information, the Glenoid Polyaxial Non-Locking Screws are substantially equivalent to the identified predicate devices.

Substantial equivalence has been demonstrated through a comparison of intended use, design, and technological characteristics, as well as performance evaluations. The Glenoid Polyaxial Non-Locking Screws implants are as safe and effective as the predicate devices Medacta Glenoid Polyaxial Locking Screw (K170452), DePuy Delta Xtend™ (K062250 and K071379), Lima SMR™ Modular Shoulder Replacement System (K100858), and Wright Medical - Tornier AEQUALIS™ REVERSED II Shoulder Prosthesis (K112144).