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**510(k) Premarket Notification
Summary of Safety and Effectiveness
for the
Osteonics® All Polyethylene Glenoid Shoulder Component**

Submission Information

**Name and Address of the Sponsor
of the 510(k) Submission:**

Osteonics Corporation
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Contact Person:

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Regulatory Affairs Specialist

Date of Summary Preparation:

May 28, 1996

Device Identification

Proprietary Name:

Osteonics® All Polyethylene Glenoid
Shoulder Component

Common Name:

Total Shoulder Glenoid Component

Classification Name and Reference:

Shoulder Joint Metal/Polymer
Semi-Constrained Cemented
Prosthesis
21 CFR §888.3660

Predicate Device Identification

The keeled Osteonics® All Polyethylene Glenoid Shoulder Components are substantially equivalent to the following competitive and/or Osteonics devices, which have previously been determined substantially equivalent by FDA:

- Osteonics® All Polyethylene Glenoid Shoulder Components: Osteonics Corp.
- Global™ Total Shoulder Glenoid Component: DePuy Inc.

Device Description

The keeled Osteonics® All Polyethylene Glenoid Shoulder Component is intended for cemented fixation within the surgically prepared glenoid fossa of the shoulder.

The Osteonics® All Polyethylene Glenoid Shoulder Component is shaped to conform to the geometry of the glenoid fossa. Its medial surface is curved so that, when placed against the prepared glenoid cavity, the device conforms to the shape of the cavity. This conformity allows less bone removal and may provide the component with added stability.

The spherical radius of the bearing surface Osteonics® All Polyethylene Glenoid Shoulder Component is larger than the spherical radius of the mating humeral head. This is intended to allow translation.

The Osteonics® All Polyethylene Glenoid Shoulder Component comes in a range of sizes. Each component features a pre-assembled, x-ray marking wire on its medial surface. Each component features a keeled fixation post.

The body of the Osteonics® All Polyethylene Glenoid Shoulder Component is manufactured from ASTM F-648 ultra-high molecular weight polyethylene (UHMWPE). The x-ray marking wire is manufactured from ASTM F-90 cobalt chromium alloy.

Intended Use:

The Osteonics® All Polyethylene Shoulder Glenoid Components are single-use devices. They are intended for cemented fixation within the prepared glenoid fossa of the shoulder.

The Osteonics® All Polyethylene Glenoid Shoulder Components, in conjunction with their mating humeral components, are intended for total shoulder arthroplasty. The indications for use are as follows:

Indications:

- Aseptic necrosis of the humeral head.
- Painful, disabling joint disease of the shoulder resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Proximal humeral fracture and/or dislocation.
- Revision of previous unsuccessful total shoulder replacement, resurfacing or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

Statement of Technological Comparison:

The technological characteristics of the subject Osteonics® All Polyethylene Glenoid Shoulder Components compare to those of the predicate devices as follows:

Materials:

The subject Osteonics® All Polyethylene Glenoid Shoulder Components, as well as all of the competitive predicate devices cited above, are made from polyethylene.

Design:

With regard to design, the subject devices are the same as the predicate Osteonics devices, except that the subject devices feature a keeled fixation post, whereas the predicate components feature fixation pegs. However, keeled post designs are common to several other legally marketed glenoid components, including the competitive predicate device identified above.

Intended Use:

The subject devices share the same intended uses as the predicate Osteonics device identified above.