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510(k) Premarket Notification
Summary of Safety and Effectiveness
for the
Osteonics® Shoulder Humeral Components

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Osteonics Corporation 59 Route 17 Allendale, NJ 07401-1677
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Device Identification

Proprietary Name:	Osteonics® Shoulder Humeral Components
Common Name:	Artificial shoulder humeral component
Classification Name and Reference:	Shoulder joint metal/polymer semi-constrained cemented prosthesis 21 CFR §888.3660 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis 21 CFR §888.3690

Predicate Device Identification

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

- The Osteonics® Shoulder Humeral Components - Osteonics Corp.
- The Global Shoulder - DePuy Inc.
- The Bio-Modular Total Shoulder - Biomet Inc.
- Monospherical Shoulder Prosthesis - Howmedica Inc.

Device Description

Each Osteonics® Shoulder Humeral Component consists of an Osteonics® Shoulder Humeral Stem and a mating Osteonics® Shoulder Humeral Head.

The Osteonics® Shoulder Humeral Stems:
The Osteonics® Shoulder Humeral Stems are available in a range of sizes, and are manufactured from Ti6Al4V alloy. They are characterized by the following features:

- Male Taper: The humeral stem components are affixed to the modular humeral head components by means of a male/female taper lock.
- Flanges: There are flanges on the anterior, posterior and lateral sides.
- Collar: The collar seats flush with the prepared proximal humerus. There are two collar designs.
- Proximal surface roughening: The surface of the proximal portion of the stem is grit blasted to enhance the cement/prosthesis interface.
- Distal Flats: The distal flats provide rotational stability.

The Osteonics® Shoulder Humeral Heads:
The Osteonics® Shoulder Humeral Heads feature a female taper design. The heads are available in a range of sizes and thicknesses. The heads feature a circular groove in the non-articulating underside of the component to prevent the components from being unnecessarily heavy. The humeral head components, which are manufactured from cobalt chromium alloy, will be available with or without nitrogen ion implantation.

Intended Use:

Each Osteonics® Shoulder Humeral Component consists of a humeral stem component and a mating humeral head component. Each device is a single-use device. The Osteonics® Shoulder Humeral Components are intended for cemented or cementless applications.

The Osteonics® Shoulder Humeral Components may be used as a hemi- or as a total shoulder replacement device. If used as a hemi-shoulder replacement device, the Osteonics® Shoulder Humeral Components are intended to articulate directly with the anatomic glenoid. If used as a total shoulder replacement device, the Osteonics® Shoulder Humeral Components are intended to articulate with the legally marketed Osteonics® All Polyethylene Glenoid Shoulder Component.

The specific indications for the use of the Osteonics® Shoulder Humeral Components are as follows:

- 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 subject devices do not differ in terms of their intended uses from the predicate devices cited earlier in this summary. The subject devices utilize the same materials as one or more of the predicate devices cited above. The subject devices employ design features which are common to one or more of the predicate devices cited above. In addition, the Osteonics® Shoulder Humeral Heads in a version with a nitrogen ion implanted bearing surface can be found substantially equivalent because the use of Nitrogen ion implantation for cobalt chromium bearing surfaces has already been found substantially equivalent by FDA for both hip femoral bearing and knee femoral bearing surfaces.