

K963671

510(k) Premarket Notification
Summary of Safety and Effectiveness
for the
Osteonics® Flanged Polyethylene Acetabular Cups

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

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Contact Person:

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Date of Summary Preparation:

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Device Identification**Proprietary Name:**

Osteonics® Flanged Polyethylene
 Acetabular Cups

Common Name:

Artificial Acetabular Component

Classification Name and Reference:

Hip joint metal/polymer semi-
 constrained cemented prosthesis
 21 CFR §888.3350

Device Panel/Product Code:

87 JDI: Prosthesis, Hip, Semi-
 constrained, Metal/polymer,
 Cemented

Predicate Device Identification

The Osteonics® Flanged Polyethylene Acetabular Cups are substantially equivalent to the following competitive and/or Osteonics devices, which have previously been determined substantially equivalent by FDA:

- Osteonics® All Polyethylene Acetabular Cups
- DePuy Ogee® Acetabular Cups

Device Description

The key features of the Osteonics® Flanged Polyethylene Acetabular Cups are:

- **Size range:** The cups are available in outer diameter (O.D.) sizes ranging from 40 - 64mm, and inner diameter (I.D.) sizes of 22, 26, and 28mm.
- **Materials:** The body of each cup is made from ultra-high molecular weight polyethylene (UHMWPE). Each cup features a cobalt chromium alloy x-ray marker wire.
- **Flanged design:** The peripheral flange pressurizes the bone cement which may, in turn, improve the cement/bone interdigitation. The flange can be trimmed intraoperatively for a customized fit.
- **Cement spacers:** The outer/back face of the cup features cement spacers that are formed during production by machined cuts made upon the surface of the cup. The spacers facilitate attainment of a uniform cement mantle.

Intended Use:

The Osteonics® Flanged Polyethylene Acetabular Cups are single-use devices which are intended for cemented fixation within the prepared acetabulum. The Osteonics® Flanged Polyethylene Acetabular Cups are compatible with any appropriately selected Osteonics hip stem/femoral head combination.

Indications:

The indications for the use of this acetabular component, in keeping with those of other legally marketed Osteonics acetabular components, are as follows:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Statement of Technological Comparison:

The substantial equivalence of the Osteonics® Flanged Polyethylene Acetabular Cups to the predicate devices identified above - in terms of materials, intended uses, and design features - is based on the following.

Materials:

Both the subject and the predicate devices are manufactured from ultra-high molecular weight polyethylene, and feature x-ray marker wires.

Intended Use:

The subject devices and both of the predicate devices are intended for cemented use only. The subject devices and the predicate Osteonics devices identified above feature the same indications for use.

Design:

A comparison of the subject device against the predicate devices identified above demonstrates that the devices are substantially equivalent in terms of design features. All of these devices are, essentially, all-polyethylene cups. Each device features a rim or flange for increased cement pressurization. The flanges featured on the subject device and on the predicate Ogee Cup have been designed to allow the surgeon to trim them, as required, to intraoperatively address the specific patient's anatomy. Both the subject device and the predicate Osteonics® All Polyethylene Acetabular Cup feature cement spacers to facilitate the attainment of a uniform cement mantle. Both the subject device and the predicate devices come in a range of outer diameter and inner diameter size combinations to accommodate a wide range of patient anatomies.

Performance Data:

Comparative tests have been performed to evaluate the push-out strength, the torsional strength and the cement pressurization attainable with the subject devices. These tests have proven, with respect to these characteristics, that the subject devices are substantially equivalent to the cited predicate devices.