510(k) Premarket Notification
Summary of Safety and Effectiveness
for the
Osteonics® Modular Acetabular Cup
(HA-Coated Version)

K963959

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Submission Information

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Device Identification

Proprietary Name:	Osteonics® Modular Acetabular Cup
Common Name:	Artificial Acetabular Component
Classification Name and Reference:	Hip Joint, Metal/Ceramic/Polymer, Semi-Constrained, Cemented or Non-porous Uncemented Prosthesis 21 CFR §888.3353

Predicate Device Identification

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

- Osteonics® Secur-Fit™-HA PSL® Shells: Osteonics Corporation.
- Osteonics® Restoration GAP Acetabular Cups: Osteonics Corporation.
- Osteonics® Omnifit® Cup Inserts: Osteonics Corporation.

Device Description

The Osteonics® Modular Acetabular Cup components are single-use devices. Each Osteonics® Modular Acetabular Cup consists of two pieces: an Osteonics® Secur-Fit™-HA PSL® ABC Shell, and a mating Osteonics® ABC Cementable Polyethylene Insert.

Intended Use:

The Osteonics® Secur-Fit™-HA PSL® ABC Shell is intended for cementless fixation within the prepared acetabulum. Osteonics® ABC Cementable Polyethylene Insert is intended for cemented assembly to the metal shell. The Osteonics® Modular Acetabular Cup is compatible with any appropriately selected Osteonics hip stem/femoral head combination. In addition, the Osteonics® ABC Cementable Polyethylene Insert - because its assembly method is independent of the inner geometry of the mating shell - is compatible with any commercially available Osteonics metal acetabular shell component.

Indications:

The indications for the use of the Osteonics® Modular Acetabular Cup, 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® Modular Acetabular Cup components to the predicate devices identified above - in terms of materials, intended uses, and design features - is based on the following.

Materials:

Osteonics® Secur-Fit™-HA PSL® ABC Shells

The Osteonics® Secur-Fit™-HA PSL® ABC Shells, like the predicate Osteonics® Secur-Fit™-HA PSL® Shells, are manufactured from CP Titanium, and feature an outer coating of arc-deposited CP Titanium and a plasma-sprayed coating of hydroxylapatite.

Osteonics® Cementable Polyethylene Inserts

The mating Osteonics® Cementable Polyethylene Inserts, like the predicate Osteonics® Omnifit® Cup Inserts (Series II) are manufactured from UHMWPE.

Intended Use:

Osteonics® Secur-Fit™-HA PSL® ABC Shells

The subject Osteonics® Secur-Fit™-HA PSL® ABC Shells and the predicate Osteonics® Secur-Fit™-HA PSL® ABC Shells share the same indications for use, and both shells are intended for cementless fixation within the prepared acetabulum.

Osteonics® Cementable Polyethylene Inserts

The Osteonics® ABC Cementable Polyethylene Inserts and the predicate Osteonics® Omnifit® Cup Inserts share the same indications for use. The Osteonics® ABC Cementable Polyethylene Inserts are intended for cemented assembly to their mating shells. This assembly method is predicated by the commercially available Osteonics® Omnifit® Cup Inserts (Series II), which have been determined substantially equivalent for cemented assembly to the commercially available Osteonics® Restoration GAP Acetabular Shells.

Design:

Osteonics® Secur-Fit™-HA PSL® ABC Shells

The subject Osteonics® Secur-Fit™-HA PSL® ABC Shell differs most notable from the commercially available Osteonics® Secur-Fit™-HA PSL® Shell with regard to its interior geometry. The subject device has a tapered interior geometry, and is intended to receive a cementable polyethylene insert.

Both the subject Osteonics® Secur-Fit™-HA PSL® ABC Shells and the predicate Osteonics® Secur-Fit™-HA PSL® Shells are manufactured from the same materials, feature the same basic shape, and feature the same Osteonics' AD-HA coating.

Osteonics® ABC Cementable Polyethylene Inserts

The Osteonics® ABC Cementable Polyethylene Inserts have several features which make them relatively more amenable to the cemented assembly method than their predicate inserts. These features include:

- Machined-in grooves: These grooves allow interdigitation with the bone cement.
- Roughened outer/back surface: The back/outer surface of the insert has been roughened to provide a stronger insert/cement interface than would be characteristic of a smoother polyethylene surface.

Neither the machined-in grooves, nor the roughened finish of the outer surface raise any new questions with regard to safety or effectiveness; both of these features are routinely employed in commercially available, one-piece, all-polyethylene acetabular cup designs.

Both the subject Osteonics® ABC Cementable Polyethylene Inserts and the predicate Osteonics® Omnifit® Cup Inserts (Series II) maintain a bearing area polyethylene thickness which is ≥6mm. Both the subject and the predicate inserts come in a wide range of inner diameter and outer

diameter sizes. Both the subject and the predicate inserts come in versions with a 0°, 10°, or 20° hooded face.

Performance Data:

Laboratory testing was undertaken to characterize the push-out strength of the Osteonics® Cementable Polyethylene Inserts when assembled to their mating acetabular shells. The test results demonstrate that the shell/insert assembly method for the Osteonics® Modular Acetabular Cup components is comparable in terms of push-out strength to predicate shell/insert assembly methods and mechanisms.