JAN 27 1997

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

K963946

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Osteonics Corporation 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Terry Sheridan Regulatory Affairs Specialist
Date of Summary Preparation:	October 1, 1996

Device Identification

Proprietary Name:	Osteonics® Modular Acetabular Cup
Common Name:	Artificial Acetabular Component
Classification Name and Reference:	Hip Joint Metal/Polymer/Metal Semi-Constrained, Porous Coated, Uncemented Prosthesis 21 CFR §888.3358

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® Omnifit® PSL® MicroStructured® 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® PSL® MicroStructured® ABC Shell, and a mating Osteonics® ABC Cementable Polyethylene Insert. The metal shell is intended for cemented or cementless fixation within the prepared acetabulum. The polyethylene insert is intended for cemented assembly to the metal shell.

Intended Use:

The Osteonics® Modular Acetabular Cup components are single-use devices. The polyethylene insert is intended for cemented assembly to the metal shell. The metal shell is intended for cemented or cementless fixation within the prepared acetabulum. 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 System components to the predicate devices identified above - in terms of materials, intended uses, and design features - is based on the following.

Materials:

Osteonics® PSL® MicroStructured® ABC Shells

The Osteonics® PSL® MicroStructured® ABC Shells, like the predicate Osteonics® Omnifit® PSL® MicroStructured® Shells are manufactured from ASTM F-67 Commercially Pure Titanium, and feature a beaded, porous coating of ASTM F-67 CP Titanium beads.

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

Intended Use:
Osteonics® PSL® MicroStructured® ABC Shells
The subject Osteonics® PSL® MicroStructured® ABC Shells and the predicate Osteonics® Omnifit® PSL® MicroStructured® Shells share the same indications for use, and both shells are intended for cemented or cementless fixation within the prepared acetabulum.

Osteonics® ABC Cementable Polyethylene Inserts
The subject 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® PSL® MicroStructured® ABC Shells
The subject Osteonics® PSL® MicroStructured® ABC Shells differ most notably from the commercially available Osteonics® Omnifit® PSL® MicroStructured® Shells with regard to their interior geometries. The subject device has a tapered interior geometry, and is intended to receive a cementable polyethylene insert.

Both the subject Osteonics® PSL® MicroStructured® ABC Shells and the predicate Osteonics® Omnifit® PSL® MicroStructured® Acetabular Shells are manufactured from the same materials, feature the same basic shape, and feature the same Osteonics® MicroStructured® 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® ABC 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.