

K960025

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510(k) Premarket Notification  
Summary of Safety and Effectiveness  
for  
Protek Low Profile Acetabular Cup

In accordance with the Food and Drug Administration Interim Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21CFR 807, this is to serve as a 510(k) Summary for the Protek Low Profile Acetabular Cup.

**Submitter:** Intermedics Orthopedics, Inc.  
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**Proprietary name** Protek Low Profile Acetabular Cup

**Common Name:** Total hip replacement acetabular component

**Classification name:** Prosthesis, Hip, Semi-constrained,  
Metal/Polymer, Cemented (21CFR  
888.3350).

**Predicate Devices:** The features employed by Protek Low Profile Acetabular Cup are substantially equivalent to the features employed by the following predicate legally marketed devices:

- Apollo All Poly Hooded Acetabular Component: Intermedics Orthopaedics Inc. (510(k) #K933203).
- Richards Cemented Acetabular Component: Smith and Nephew Richards (510(k) number unknown to IOI).
- Osteonics All Poly Acetabular Cup: Osteonics Corporation (510(k) number unknown to IOI).
- Ultima Polyethylene Acetabular Cup: Johnson & Johnson Orthopaedics (510(k) number unknown to IOI).

**Device Description:**

The Protek Low Profile Acetabular Cup (Catalog No. ) is fabricated from ultra high molecular weight polyethylene (UHMWPE). The Protek Low Profile Acetabular Cup is spherical in design and employs longitudinal cement channels and circumferential cement grooves along the outer surface of the cup. The longitudinal cement channels and vertical grooves provides greater cement interdigitation with PMMA bone cement. In addition, the Protek Low Profile Acetabular Cup employs radiographic marker wires along the periphery of the outer rim and on the superior outer portion of the acetabular cup.

The smaller sizes of the Protek Low Profile Acetabular Cup [Sizes 22mm (ODs' 36, 38, and 40mm), 28mm (OD 42mm), and 32mm (ODs' of 44 and 46mm)], with a minimum polyethylene thickness of 6mm are intended only for use with the Protek acetabular reinforcement devices which are utilized in patients with acetabular bone deficiencies. The Protek acetabular reinforcement devices have been determined substantially equivalent by the FDA via 510(k) #K953578.

The Protek Low Profile Acetabular Cup is available in inner diameters of 22, 28, and 32mm, with outer diameter sizes ranging from 36 to 64mm with 2mm increments.

**Intended Use:**

The Protek Low Profile Acetabular Cup, like the predicate acetabular components, is intended for cemented fixation within the prepared acetabulum. The Indications for Use for the Protek Low Profile Acetabular Cup are as follows:

- Advanced Joint destruction resulting from degenerative, posttraumatic or rheumatoid arthritis.
- Fracture or avascular necrosis of the femoral head.
- Failed previous surgery, e.g. osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty and total hip replacement.

**Summary of Technological Characteristics:**

The features of the Protek Low Profile Acetabular Cup are substantially equivalent to the aforementioned predicate Protek and/or competitive devices in terms of materials, intended use and design characteristics. A comparison of the features of the Protek Low Profile Acetabular Cup in terms of materials, intended use and design characteristics to the aforementioned predicate devices is as follows:

Materials:

Substantial equivalence in terms of materials is based upon the fact that both the subject device and the legally marketed predicate devices are fabricated from ultra high molecular weight polyethylene (UHMWPE).

Intended Use:

The Protek Low Profile Acetabular Cup, like the predicate acetabular components, is intended for cemented application. The subject device and the predicate devices share the same indications for use. Therefore, in terms of intended use the subject device is substantially equivalent to the legally marketed predicate devices.

Design characteristics:

The Protek Low Profile Acetabular Cup, like the predicate acetabular components, is spherical in design and employs longitudinal cement channels along the outer surface of the cup. Therefore, in terms of design characteristics the subject device is substantially equivalent to the legally marketed predicate devices.

A side by side tabular comparison of the features of the Protek Low Profile Acetabular Cup to those of the predicate devices follows.