

K955739

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Modular Acetabular Shell II.

**Submitter:** Intermedics Orthopedics, Inc.  
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**Classification Name:** Hip Joint Metal/Polymer/Metal Semi-constrained Porous-coated Uncemented Prosthesis, 21CFR 888.3358

**Common/Usual Name:** Acetabular shell

**Trade/Proprietary Name:** Modular Acetabular Shell II

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### PRODUCT DESCRIPTION/SUBSTANTIAL EQUIVALENCE

The Modular Acetabular Shell II is a metal hemispherical shell manufactured from Ti-6Al-4V alloy and coated with Cancellous Structured Titanium™ (CSTi™). This device may be implanted with or without bone cement and will be used in conjunction with a snap-in acetabular insert manufactured from ultra-high molecular weight polyethylene (UHMWPE). In order to address various clinical situations, these inserts are available in standard, hooded and hooded protrusio designs.

The Modular Acetabular Shell II may be implanted in a solid configuration or in a screw hole configuration. The shell is provided with screw hole plugs which are sintered in place. The screw hole plugs can be removed intraoperatively before or after implantation if the surgeon opts to enhance fixation of the shell with bone screws.

Testing was conducted which demonstrated that the integrity of the screw hole plug bonds was maintained under fatigue loading conditions. Additionally, the inside surface of the screw hole, upon removal of the plug, was shown to be comparable to the screw hole surfaces of currently marketed devices.

The integrity of the locking mechanism of the Modular Acetabular Shell II was investigated by examining the attachment strength between the acetabular shell and acetabular insert. The strength of the locking mechanism compares favorably to other currently marketed devices.

The Modular Acetabular Shell II is substantially equivalent to the Option Shell (Intermedics Orthopedics, Inc.). Furthermore, the concept of providing the surgeon with an acetabular component which may be implanted in a solid configuration or in a screwhole configuration is substantially equivalent to the concept behind the Acetabular Dome and Screw Hole Plugs (Osteonics®). Additionally, with the screwhole plugs removed, the Modular Acetabular Shell II is substantially equivalent to the APR® Acetabular Shell (Intermedics Orthopedics, Inc.). In its solid configuration, the Modular Acetabular Shell II is substantially equivalent to the Non-Holed design of the Trilogy Acetabular System (Zimmer, Inc.).