

K961388

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510(k) SUMMARY - ATLAS® III Acetabular Cup

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Device Trade Name: ATLAS® III Acetabular Cup

Device Common Name: Acetabular Cup

Classification Name: Prosthesis, Hip, Acetabular Component,
Ultra High Molecular Weight Polyethylene

Predicate Devices: Hydroxylapatite McCutchen Acetabular Cup
Dow Corning Wright
(K912452)

Omnifit-HA Acetabular Cup
Osteonics Corp.
(K911728)

Secure-Fit HA PSL Extra Acetabular
Component System
Osteonics Corp.
(K954023)

Device Description: The ATLAS® III Acetabular Cup is available in twelve (12) outer diameter (O.D.) sizes from 46 mm to 68 mm in two (2) mm increments. The polyethylene insert is available in four (4) possible inner diameter (I.D.) size options, 22.2 mm, 26 mm, 28 mm and 32 mm. The ATLAS® III Acetabular Cup instrumentation system is utilized for proper impaction of the device.

Intended Use: The ATLAS® III Acetabular Cup is intended for use in degenerative and inflammatory arthritis of the hip joint, trauma, and revision of previously failed hip arthroplasties. The device is designed for cementless application.

Device Technological Characteristics and Comparison to Predicate Devices:

The ATLAS® III Acetabular Cup design includes eight (8) axial screw holes, four (4) locking pegs for anchoring the device during impaction, one (1) dome hole for verifying impaction, and a two (2) millimeter slot which closes up after impaction to assist implant stability. The use of screws for implant stability is optional and determined by the surgeon at the time of impaction. The polyethylene insert is placed into the acetabular shell by the surgeon once the shell is successfully impacted.

Identified predicate devices have the same intended use and may incorporate some or all of the above described design features either alone or in combination.

Performance Data:

Testing conducted to characterize the materials, the hydroxylapatite coating, and the performance characteristics of the device under defined laboratory conditions was provided to support a finding of substantial equivalence.

Conclusion:

The ATLAS® III Acetabular Cup is substantially equivalent to predicate devices in terms of intended use, safety and effectiveness.