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**510(k) Summary of
Safety and Effectiveness**

K955137

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Product: Classification Name: Acetabular Component of Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis (21 CFR 888.3350)

Generic Name: Acetabular Component of a Cemented Total Hip Replacement

Trade/Proprietary Name: IM C-Ment Acetabular Cup

Substantially Equivalent Products:

M.E. Muller Type Acetabular Cups from DePuy
Charnley Type Acetabular Cup from DePuy
New England Baptist Hip Cups from DePuy

Description: The IM C-Ment Acetabular Cup is an all-polyethylene, hemispherical acetabular component with three (3) concentric grooves on the outer diameter and 3 circular indentations equally-spaced around the circumference near the middle of the cup. It is provided in eleven (11) sizes for the 28mm inner diameter, ranging from outer diameters of 40mm to 60mm.

Intended Use: The IM C-Ment Acetabular Cup will be used in indications which are the same as that for other acetabular components of cemented total hip replacement systems. Specifically, the IM C-Ment Acetabular Cup is intended to resurface the acetabular socket in cases of femoral head and neck fractures, nonunion of femoral head and neck fractures, femoral head aseptic necrosis, osteoarthritis, rheumatoid arthritis and revision of failed prostheses.

The IM C-Ment Acetabular Cup is intended to be used in cemented applications only.

Comparison to Substantially Equivalent Products:

All of the named acetabular cups use UHMWPE and Stainless Steel materials. These materials have a history of demonstrated success as implant materials for acetabular cups.

The IM C-Ment Acetabular Cup is available in an inner diameter of 28mm. The other three cups have inner diameters of 22mm and 32mm. The IM C-Ment Acetabular Cup is available in outer diameters between 40 and 60mm. This is within the range of outer diameter sizes represented by the other three cups, i.e., 36 to 65mm.

All of the named acetabular cups are used to reconstruct the hip joint in combination with a femoral stem and head to provide appropriate joint spacing and femoral/acetabular articulation. In addition, all of the products are intended to be used in cemented applications.

All of the named acetabular cups are hemispherical, with a concentric I.D., concentric cement grooves, circular x-ray wires. The only exceptions to this are:

1. The New England Baptist Hip Cup has an eccentric I.D. and uses two circular x-ray wires rather than one.