

K961186

SUMMARY OF SAFETY AND EFFECTIVENESS

**NAME OF FIRM:** DePuy Inc.  
P.O. Box 988  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988

**FIRM CONTACT:** Sally Foust  
Clinical Research Specialist

**TRADE NAME:** DePuy Duraloc® Acetabular Cups - the Bantam, Sector, Polished Sector, Polished Sector, Full Profile Sector, and Deep Profile Solutions Cups

**COMMON NAME:** Acetabular Cup Prosthesis

**CLASSIFICATION:** 888.3358 Hip joint metal/polymer semi-constrained cementless prosthesis

**DEVICE PRODUCT CODE:** 87 LPH

**SUBSTANTIALLY EQUIVALENT DEVICES:**

- ▶ Depuy Duraloc® Cementless Acetabular Cup System
- ▶ Modified DePuy Acetabular Cup System

**DEVICE DESCRIPTION AND INTENDED USE:**

The subject DePuy Duraloc Acetabular Cups are porous coated Ti-6Al-4V alloy acetabular cups which are available in various sizes, ranging from 38mm to 80mm in outer diameter. All of the cups have screw holes, either dome or peripheral, for adjunctive fixation. All of the DePuy Duraloc Acetabular Cups are intended to be used with DePuy Duraloc polyethylene liners and locking rings to resurface the acetabular socket in cemented or cementless total hip replacement.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

The DePuy Duraloc Acetabular Cups are substantially equivalent to the DePuy Duraloc Acetabular 1200 Cups cleared for both cementless fixation and cemented fixation (under the name Modified DePuy Acetabular Cup). All of the subject Duraloc Acetabular Cups and the Duraloc 1200 Cup are manufactured from Ti-6Al-4V alloy with a CP Titanium porous coating. All are available in numerous and varying outer diameters ranging from 38mm to 80mm and are designed to be used with the Duraloc polyethylene liners.

The only differences between the subject DePuy Duraloc Acetabular Cups and the Duraloc 1200 Cups are the addition of smaller outer diameter options with the Bantam cups; the number/and or placement of screw holes with the Bantam, Sector and Deep Profile Solution cups; the polished inner surface of the Polished Sector cups; and the full 180 degree hemispherical profile of the Full Profile Sector and Deep Profile Solution acetabular cups.

000016