

510K SAFETY AND EFFECTIVENESS SUMMARY

K963309

NAME OF FIRM:

DePuy Inc.
P.O. Box 988
Warsaw, IN 46581-0988

NOV 12 1996

510(k) CONTACT:

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Manager, Clinical Affairs

TRADE NAME:

Apex Hole Eliminator PS

CLASSIFICATION NAME:

Prosthesis, Hip, Semi-constrained (metal uncemented) Acetabular Component
(Regulation number: 888.3330)

SUBSTANTIALLY EQUIVALENT DEVICES: DePuy Duraloc® 100C Acetabular Cup

Wright Medical Interseal™ Acetabular Components

INTENDED USE AND DEVICE DESCRIPTION:

The Apex Hole Eliminator PS is a threaded plug intended to close the apical hole of the Duraloc® series two-piece acetabular cups. It is intended for use in Duraloc cups implanted with or without bone cement. It can be used after insertion of the acetabular cup in a cementless technique once the cup is well seated to prevent movement of blood or particles from behind the shell through the hole or it can be placed prior to insertion of the cup if the cup is being cemented into place to prevent cement from coming through the apical hole. The Apex Hole Eliminator PS also provides support of the polyethylene liner utilized in the metal shell, assuring full, congruent, uninterrupted support of the liner within the shell, and eliminating the potential of cold flow of the liner into the apical hole of the metal shell.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Apex Hole Eliminator PS is substantially equivalent to the apical hole plug which was cleared with the DePuy Duraloc 100C Acetabular Cup and to the apical hole plug used with the Wright Medical Interseal Acetabular Components in that they have similar designs and the same intended use. The differences between the Apex Hole Eliminator PS and the Duraloc 100C apical hole eliminator are: 1) the Apex Hole Eliminator PS is manufactured from forged Ti-6Al-4V while the Duraloc 100C apical hole eliminator is manufactured from forged Co-Cr-Mo; and 2) the Apex Hole Eliminator PS has standard threads and a taper on the trailing edge to lock it into the acetabular shell. The Duraloc 100C apical hole eliminator has interference locking threads to fasten it to the acetabular shell.