

FEB 13 1997

510(k) Summary

K963940

Proprietary Name: Exeter Mesh

Common Name: Prosthesis, Hip, Acetabular Mesh

Classification Name and Reference: 21 CFR 878.3300  
Prosthesis, Hip, Acetabular Mesh

Proposed Regulatory Class: Class II

Device Product Code: ~~OR(87)~~ JDJ  
SU(79)

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The Exeter Mesh is intended to be used to reinforce bone when additional strengthening and support is required. The Exeter Mesh is available in four (4) styles to fit a variety of anatomical requirements. The mesh is intended to be either cemented in place or affixed with screws. Screws are provided that are 3.5mm in diameter and range in length from 10mm to 35mm.

Substantial equivalence of the Exeter Mesh is based on the equivalence in intended use, materials, design, operational principles, and indications and contraindications to Howmedica's Acetabular mesh (preamendment), and mesh marketed by Osteonics (K925883) and Intermedics (K890450).