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510(k) SUMMARY - HEDROCEL® ACETABULAR RESTRICTOR

Submitter Name:	Implex Corp.
Submitter Address:	80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person:	Robert Cohen, Vice President, Product Development
Phone Number:	(201) 818-1800
Fax Number:	(201) 818-0567
Date Prepared:	November 21, 1996
Device Trade Name:	Hedrocel® Acetabular Restrictor
Device Common Name:	Prosthesis, Hip, Cement Restrictor
Classification Name:	Surgical Mesh (per CFR § 878.3300)
Predicate Devices:	Zimmer Cement Restrictor #4043-20 Howmedica Charnley Cement Restrictor Motech Titanium Surgical Mesh
Device Description:	The Hedrocel® Acetabular Restrictor is manufactured as a surgical mesh fabricated from Hedrocel® porous metal. The tantalum lattice mesh device is available in three (3) sizes. The Hedrocel® material is a tantalum deposited upon vitreous carbon construct which possesses dodecahedron shaped, fully interconnecting pores resulting in a relatively high bulk volume porosity, approximately 80%. Cement restrictors are classified as Surgical Meshes.
Intended Use:	The Hedrocel® Acetabular Restrictor is a device intended for restriction of effusion of bone cement, allograft bone, and/or autograft bone into the pelvis if defects in the acetabulum are encountered.
Device Technological Characteristics and Comparison to Predicate Devices:	The design features of the Hedrocel® Acetabular Restrictor are identical to the predicate devices. For example, these devices all use an open lattice design and are fabricated from metallic alloys. The specific alloys utilized varies among the devices. The Hedrocel® Acetabular Restrictor is manufactured using a process in which tantalum is deposited onto a reticulated vitreous carbon (RVC) skeleton.
Conclusion:	The Hedrocel® Acetabular Restrictor is substantially equivalent to predicate devices in terms of intended use, safety, and effectiveness.