

**K023400 FCI MESH WRAPPED BIOCERAMIC ORBITAL
IMPLANT**Aug 22, 2003
317 days to decisionK023400 · Product code: **HPZ** · Ophthalmic
Source: <https://www.510kdatabase.net/k023400/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Eye Sphere (HPZ)
Date received	Oct 9, 2002
Decision date	Aug 22, 2003
Days to decision	317 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Fci Ophthalmics, Inc.
Location	Centercille, MA, US
Contact	HILLARD W WELCH
510(k) history	13 submissions · 13 cleared · 1996-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k023400/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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