

K992294 BIOCERAMIC ORBITAL IMPLANTApr 19, 2000
287 days to decisionK992294 · Product code: **HPZ** · Ophthalmic
Source: <https://www.510kdatabase.net/k992294/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Eye Sphere (HPZ)
Date received	Jul 7, 1999
Decision date	Apr 19, 2000
Days to decision	287 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Fci Ophthalmics, Inc.
Location	Centerville, MA, US
Contact	ANNE BOHSACK
510(k) history	13 submissions · 13 cleared · 1996-2006

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