

K110554 BIOCERAMIC ORBITAL IMPLANT, ORBTEXNov 2, 2011
247 days to decisionK110554 · Product code: **HPZ** · Ophthalmic
Source: <https://www.510kdatabase.net/k110554/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Eye Sphere (HPZ)
Date received	Feb 28, 2011
Decision date	Nov 2, 2011
Days to decision	247 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ceramisisys, Ltd.
Location	Centerville, MA, US
Contact	HILLARD W WELCH
510(k) history	2 submissions · 2 cleared · 2011-2011

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