

K053298 ALPHASPHERE ORBITAL IMPLANTMay 9, 2006
165 days to decisionK053298 · Product code: **HPZ** · Ophthalmic
Source: <https://www.510kdatabase.net/k053298/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Eye Sphere (HPZ)
Date received	Nov 25, 2005
Decision date	May 9, 2006
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hydron Pty Limited
Location	Laguna Beach, CA, US
Contact	JUDY F GORDON
510(k) history	1 submissions · 1 cleared · 2006-2006

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