

K083342 ORBITAL RECONSTRUCTIVE IMPLANT IIMar 12, 2009
120 days to decisionK083342 · Product code: **HPZ** · Ophthalmic
Source: <https://www.510kdatabase.net/k083342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Eye Sphere (HPZ)
Date received	Nov 12, 2008
Decision date	Mar 12, 2009
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Evera Medical, Inc.
Location	Foster City, CA, US
Contact	RANDY KESTEN
510(k) history	2 submissions · 2 cleared · 2007-2009

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