

**K972661 EYE SPHERE, CONFORMERS**Oct 3, 1997  
79 days to decisionK972661 · Product code: **HPZ** · Ophthalmic  
Source: <https://www.510kdatabase.net/k972661/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Eye Sphere (HPZ)
Date received	Jul 16, 1997
Decision date	Oct 3, 1997
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gulden Ophthalmics</b>
Location	Elkins Park, PA, US
Contact	THOMAS COCKLEY
510(k) history	1 submissions · 1 cleared · 1997-1997

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