

**K112176 SILICONE SPHERES**Sep 15, 2011  
49 days to decisionK112176 · Product code: **HPZ** · Ophthalmic  
Source: <https://www.510kdatabase.net/k112176/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Eye Sphere (HPZ)
Date received	Jul 28, 2011
Decision date	Sep 15, 2011
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Oculo Plastik, Inc.</b>
Location	Montreal, Quebec Canada, CA
Contact	SYLVAIN DESROSIERS
510(k) history	13 submissions · 13 cleared · 1990-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112176/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 9, 2026