

**K081346 HOYA IS INJECTOR SYSTEM**Mar 23, 2009  
313 days to decisionK081346 · Product code: **MSS** · Ophthalmic  
Source: <https://www.510kdatabase.net/k081346/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Folders And Injectors, Intraocular Lens (iol) (MSS)
Date received	May 14, 2008
Decision date	Mar 23, 2009
Days to decision	313 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hoya Surgical Optics, Inc.</b>
Location	Chino Hills, CA, US
Contact	STEVEN L ZIEMBA
510(k) history	1 submissions · 1 cleared · 2009-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081346/> 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 23, 2026