

**K132042 AMB101 SYSTEM, AMBLYZ, LCG SYSTEM, XPAND**Apr 28, 2014  
300 days to decisionK132042 · Product code: **HOY** · Ophthalmic  
Source: <https://www.510kdatabase.net/k132042/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shield, Eye, Ophthalmic (including Sunlamp Protective Eyewear And Post-mydratic Eyewear) (HOY)
Date received	Jul 2, 2013
Decision date	Apr 28, 2014
Days to decision	300 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>X6d, Ltd.</b>
Location	Zur- Moshe, IL
Contact	KAREL VAN GORP
510(k) history	1 submissions · 1 cleared · 2014-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132042/> 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 7, 2026