

**K072102 EPIVISION SL SYSTEM**Jan 16, 2009  
535 days to decisionK072102 · Product code: **HNO** · Ophthalmic  
Source: <https://www.510kdatabase.net/k072102/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Keratome, Ac-powered (HNO)
Date received	Jul 31, 2007
Decision date	Jan 16, 2009
Days to decision	535 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gebauer Medizintechnik GmbH</b>
Location	Lexington, MA, US
Contact	KIMBERLEY DONEY
510(k) history	2 submissions · 2 cleared · 2004-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k072102/> 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