

**K913697 AUTOMATIC CORNEAL SHAPER**Nov 5, 1991  
78 days to decisionK913697 · Product code: **HNO** · Ophthalmic  
Source: <https://www.510kdatabase.net/k913697/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Keratome, Ac-powered (HNO)
Date received	Aug 19, 1991
Decision date	Nov 5, 1991
Days to decision	78 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hansa Research &amp; Development, Inc.</b>
Location	Miami, FL, US
Contact	BRIGITTA HELLENKAMP
510(k) history	1 submissions · 1 cleared · 1991-1991

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k913697/> 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 30, 2026