

**K131787 CRYOMATIC MKII CONSOLE, CRYOMATIC MKII PROBES, DISPOSABLE CRYO PROBES**Dec 23, 2013  
188 days to decisionK131787 · Product code: **HRN** · Ophthalmic  
Source: <https://www.510kdatabase.net/k131787/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Cryophthalmic, Ac-powered (HRN)
Date received	Jun 18, 2013
Decision date	Dec 23, 2013
Days to decision	188 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Keeler, Ltd.</b>
Location	Broomall, PA, US
Contact	EUGENE R VANARSDALE
Website	<a href="http://www.keeler.co.uk/">http://www.keeler.co.uk/</a>
510(k) history	4 submissions · 4 cleared · 2010-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131787/> 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 6, 2026