

**K043150 AMADEUS II EPIKERATOME**Jan 31, 2005  
77 days to decisionK043150 · Product code: **HNO** · Ophthalmic  
Source: <https://www.510kdatabase.net/k043150/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Keratome, Ac-powered (HNO)
Date received	Nov 15, 2004
Decision date	Jan 31, 2005
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sis Ltd., Surgical Instrument Systems</b>
Location	Littleton, CO, US
Contact	Kevin Walls
510(k) history	3 submissions · 3 cleared · 2005-2009

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