

**K113073 IO-TOME DEVICE**Jul 27, 2012  
284 days to decisionK113073 · Product code: **HAE** · Neurology  
Source: <https://www.510kdatabase.net/k113073/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rongeur, Manual (HAE)
Date received	Oct 17, 2011
Decision date	Jul 27, 2012
Days to decision	284 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Baxano, Inc.</b>
Location	Yorba Linda, CA, US
Contact	EDWARD J SINCLAIR
510(k) history	10 submissions · 10 cleared · 2007-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113073/> 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 May 24, 2026