

K113533 NEURO CHECK DEVICE WITH IO-FLEX WIREApr 11, 2012
133 days to decisionK113533 · Product code: **HAE** · Neurology
Source: <https://www.510kdatabase.net/k113533/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Rongeur, Manual (HAE)
Date received	Nov 30, 2011
Decision date	Apr 11, 2012
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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