

**K152558 Leksell Stereotactic System, Injection/ Aspiration  
Needle Kit**Mar 2, 2016  
175 days to decisionK152558 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k152558/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Sep 9, 2015
Decision date	Mar 2, 2016
Days to decision	175 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Elekta Instrument AB</b>
Location	Lake Forest, CA, US
Contact	EMMA WIDMARK
510(k) history	35 submissions · 35 cleared · 1996-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152558/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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