

K190887 Leksell Vantage Stereotactic SystemAug 1, 2019
119 days to decisionK190887 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k190887/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Apr 4, 2019
Decision date	Aug 1, 2019
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Elekta Instrument AB
Location	Lake Forest, CA, US
Contact	Helena Skar
510(k) history	35 submissions · 35 cleared · 1996-2019

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