

K151159 Leksell Gamma Knife PerfexionOct 29, 2015
181 days to decisionK151159 · Product code: **IWB** · Radiology
Source: <https://www.510kdatabase.net/k151159/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Radionuclide (IWB)
Date received	May 1, 2015
Decision date	Oct 29, 2015
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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