

K173789 Leksell Gamma Knife Perfexion, Leksell Gamma Knife IconMar 30, 2018
106 days to decisionK173789 · Product code: **IWB** · Radiology
Source: <https://www.510kdatabase.net/k173789/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Radionuclide (IWB)
Date received	Dec 14, 2017
Decision date	Mar 30, 2018
Days to decision	106 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	Alf Laurell
510(k) history	35 submissions · 35 cleared · 1996-2019

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