

K173791 Leksell GammaPlanFeb 9, 2018
57 days to decisionK173791 · Product code: **IWB** · Radiology
Source: <https://www.510kdatabase.net/k173791/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Radionuclide (IWB)
Date received	Dec 14, 2017
Decision date	Feb 9, 2018
Days to decision	57 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	Matilda Forsberg
510(k) history	35 submissions · 35 cleared · 1996-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173791/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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