FDA 510(k) Premarket Notification

K151666 Leksell GammaPlan

CLEARED

Sep 3, 2015
76 days to decision

K151666 · Product code: **MUJ** · Radiology
Source: https://www.510kdatabase.net/k151666/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Jun 19, 2015
Decision date	Sep 3, 2015
Days to decision	76 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