FDA 510(k) Premarket Notification

K090972 LEKSELL GAMMAPLAN

CLEARED

Jul 20, 2009
105 days to decision

K090972 · Product code: **MUJ** · Radiology
Source: https://www.510kdatabase.net/k090972/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Apr 6, 2009
Decision date	Jul 20, 2009
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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