FDA 510(k) Premarket Notification

K080250 LEKSELL SURGIPLAN, MODEL 1006947

CLEARED

May 13, 2008
103 days to decision

K080250 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k080250/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jan 31, 2008
Decision date	May 13, 2008
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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