

K080250 LEKSELL SURGIPLAN, MODEL 1006947May 13, 2008
103 days to decisionK080250 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080250/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 18, 2026