

K010542 SNN SYSTEM INCLUDING THE TOMOGUIDE OPTIONMay 8, 2001
74 days to decisionK010542 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k010542/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Feb 23, 2001
Decision date	May 8, 2001
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Surgical Navigation Specialists, Inc.
Location	Mississauga Ontario, CA
Contact	CAROL NAKAGAWA
510(k) history	3 submissions · 3 cleared · 1999-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010542/> 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 30, 2026