

K974161 STEALTHSTATION SYSTEMNov 21, 1997
86 days to decisionK974161 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k974161/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Aug 27, 1997
Decision date	Nov 21, 1997
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Surgical Navigation Technologies, Inc.
Location	Broomfield, CO, US
Contact	DAVID A MIRE
510(k) history	27 submissions · 27 cleared · 1996-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974161/> 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 May 19, 2026