

K964801 OPTICAL TRACKING SYSTEM (OTS)Jun 2, 1997
185 days to decisionK964801 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k964801/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Nov 29, 1996
Decision date	Jun 2, 1997
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Radionics Software Applications, Inc.
Location	Brookline, MA, US
Contact	AMY J LAFORTE, PH.D.
510(k) history	12 submissions · 12 cleared · 1993-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964801/> 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 20, 2026