

**K010548 MODIFICATION TO OPTICAL TRACKING SYSTEM
(OTS)**Mar 12, 2001
14 days to decisionK010548 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k010548/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Feb 26, 2001
Decision date	Mar 12, 2001
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Radionics, A Division of Tyco Healthcare Group LP
Location	Burlington, MA, US
Contact	KEVIN J O'CONNELL
510(k) history	8 submissions · 8 cleared · 2001-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010548/>; 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 18, 2026