

**K033619 NAVIGUS UNIBODY FIDUCIAL MARKER SYSTEM,
MODEL FM-4000**Mar 2, 2004
105 days to decisionK033619 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k033619/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Nov 18, 2003
Decision date	Mar 2, 2004
Days to decision	105 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Image-Guided Neurologics, Inc.
Location	Melbourne, FL, US
Contact	DAVID M LEE
510(k) history	22 submissions · 22 cleared · 1999-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033619/>; 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