

K180206 neuromate Gen IIIApr 24, 2018
90 days to decisionK180206 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k180206/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jan 24, 2018
Decision date	Apr 24, 2018
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Renishaw Mayfield Sarl
Location	Chassieu, FR
Contact	Stephane Vinot
510(k) history	3 submissions · 3 cleared · 2014-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180206/> 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 30, 2026