

**K122211 SYNTHES NAVIGABLE PEDICLE PREPARATION
INSTRUMENTS**Dec 17, 2012
145 days to decisionK122211 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k122211/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jul 25, 2012
Decision date	Dec 17, 2012
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synthes Spine
Location	Paoli, PA, US
Contact	HEMAL MEHTA
510(k) history	36 submissions · 32 cleared · 1995-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122211/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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