

**K080547 ORTHOPILOT NEXT GENERATION, MODEL
FS101-FS106**May 23, 2008
85 days to decisionK080547 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k080547/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Feb 28, 2008
Decision date	May 23, 2008
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aesculap Implant System, Inc.
Location	Center Valley, PA, US
Contact	MATTHEW M HULL
510(k) history	18 submissions · 18 cleared · 2007-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080547/>; 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 14, 2026