FDA 510(k) Premarket Notification

K080547 ORTHOPILOT NEXT GENERATION, MODEL FS101-FS106

CLEARED

May 23, 2008
85 days to decision

K080547 · 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