FDA 510(k) Premarket Notification

K090375 ORTHOPILOT NEXT GENERATION-UKA SOFTWARE, MODEL FS210

CLEARED

Jun 23, 2009
126 days to decision

K090375 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k090375/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Feb 17, 2009
Decision date	Jun 23, 2009
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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