

K153700 Aesculap(R) Implant Systems (AIS) S4 Navigation InstrumentsJul 8, 2016
198 days to decisionK153700 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k153700/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 23, 2015
Decision date	Jul 8, 2016
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aesculap Implant Systems, LLC
Location	Center Valley, PA, US
Contact	Paul Amudala
510(k) history	22 submissions · 22 cleared · 2010-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153700/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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