

K181890 Brainlab Compatible K2M Navigation InstrumentsNov 9, 2018
119 days to decisionK181890 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k181890/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jul 13, 2018
Decision date	Nov 9, 2018
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	K2m
Location	Leesburg, VA, US
Contact	Nancy Giezen
510(k) history	16 submissions · 16 cleared · 2014-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181890/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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