

K183644 Stealth-Midas MR8 SystemMay 22, 2019
147 days to decisionK183644 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k183644/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 26, 2018
Decision date	May 22, 2019
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Powered Surgical Solutions
Location	Fort Worth, TX, US
Contact	Jenna Groves
510(k) history	9 submissions · 9 cleared · 2007-2021

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