

K191039 Navigated T2 STRATOSPHERE Inserters and Navigated TemplatesAug 26, 2019
129 days to decisionK191039 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k191039/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Apr 19, 2019
Decision date	Aug 26, 2019
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Sofamor Danek USA, Inc.
Location	Memphis, TN, US
Contact	Elizabeth Hamilton
510(k) history	170 submissions · 159 cleared · 2000-2026

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