

K182848 ROSA ONE Spine applicationMar 22, 2019
164 days to decisionK182848 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k182848/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Oct 9, 2018
Decision date	Mar 22, 2019
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtech S.A
Location	Montpellier, FR
Contact	Serge Tabet
510(k) history	8 submissions · 8 cleared · 2009-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182848/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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