FDA 510(k) Premarket Notification

K192173 ROSA ONE Spine application

CLEARED

Oct 29, 2019
78 days to decision

K192173 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k192173/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Aug 12, 2019
Decision date	Oct 29, 2019
Days to decision	78 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