FDA 510(k) Premarket Notification

K210121 ROSA Partial Knee System

CLEARED

Apr 19, 2021
90 days to decision

K210121 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k210121/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jan 19, 2021
Decision date	Apr 19, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Orthosoft D/B/A Zimmer Cas**
Location	Montreal, CA
Contact	Kavina Veeren
510(k) history	7 submissions · 7 cleared · 2021-2023