FDA 510(k) Premarket Notification

K213033 iASSIST Knee System

CLEARED

Jan 14, 2022
115 days to decision

K213033 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k213033/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Sep 21, 2021
Decision date	Jan 14, 2022
Days to decision	115 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	Paul Hardy
510(k) history	7 submissions · 7 cleared · 2021-2023