FDA 510(k) Premarket Notification

K223927 360CAS

CLEARED

Jan 27, 2023
28 days to decision

K223927 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k223927/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 30, 2022
Decision date	Jan 27, 2023
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Kico Knee Innovation Company Pty Limited**
Location	Pymble, AU
Contact	Danyon Munro
510(k) history	4 submissions · 4 cleared · 2017-2025