FDA 510(k) Premarket Notification

K234056 canturio® se (Canturio Smart Extension)

CLEARED

Apr 24, 2024
124 days to decision

K234056 · Product code: **QPP** · Orthopedic
Source: https://www.510kdatabase.net/k234056/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Post-surgical Kinematic Measurement Knee Device (QPP)
Date received	Dec 22, 2023
Decision date	Apr 24, 2024
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Canary Medical USA, LLC**
Location	Carlsbad, CA, US
Contact	Kevin Leung
510(k) history	3 submissions · 3 cleared · 2022-2024