FDA 510(k) Premarket Notification

K233542 Ortho Guidance Precision Knee Software

CLEARED

Mar 14, 2024
132 days to decision

K233542 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k233542/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 3, 2023
Decision date	Mar 14, 2024
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Ortho Guidance Express Knee Software; Ortho Guidance Versatile Hip Software; Q Guidance System

APPLICANT

Company	**Stryker Leibinger GmbH & Co KG**
Location	Freiburg Im Breisgau, DE
Contact	Megan B Guilbault
510(k) history	21 submissions · 21 cleared · 2009-2026