FDA 510(k) Premarket Notification

K150231 Navigated Disc Prep Instruments and CAPSTONE Trials

CLEARED

Jun 16, 2015
134 days to decision

K150231 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k150231/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Feb 2, 2015
Decision date	Jun 16, 2015
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Sofamor Danek USA, Inc.**
Location	Memphis, TN, US
Contact	Nicholas Tabrizi
510(k) history	170 submissions · 159 cleared · 2000-2026