FDA 510(k) Premarket Notification

K190556 Zimmer Biomet Universal Navigation System

CLEARED

Oct 24, 2019
233 days to decision

K190556 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k190556/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Mar 5, 2019
Decision date	Oct 24, 2019
Days to decision	233 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer Biomet Spine, Inc.**
Location	Broomfield, CO, US
Contact	Kelly Stratton
510(k) history	15 submissions · 15 cleared · 2017-2021