FDA 510(k) Premarket Notification

K171556 K2M Navigation Instruments

CLEARED

Jan 16, 2018
231 days to decision

K171556 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k171556/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	May 30, 2017
Decision date	Jan 16, 2018
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**K2m**
Location	Leesburg, VA, US
Contact	Nancy Giezen
510(k) history	16 submissions · 16 cleared · 2014-2018