FDA 510(k) Premarket Notification

K192014 SYPMHONY™ OCT System

CLEARED

Jan 24, 2020
179 days to decision

K192014 · Product code: **NKG** · Orthopedic
Source: https://www.510kdatabase.net/k192014/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	Jul 29, 2019
Decision date	Jan 24, 2020
Days to decision	179 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medos International SARL**
Location	Raynham, MA, US
Contact	Sheree Geller
510(k) history	96 submissions · 96 cleared · 2010-2026