FDA 510(k) Premarket Notification

K190599 Aptis Medical Distal Radio Ulnar Joint Implant

CLEARED

May 3, 2019
56 days to decision

K190599 · Product code: **KXE** · Orthopedic
Source: https://www.510kdatabase.net/k190599/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Wrist, Hemi-, Ulnar (KXE)
Date received	Mar 8, 2019
Decision date	May 3, 2019
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aptis Medical, LLC**
Location	Del Mar, CA, US
Contact	Bryan Babb
510(k) history	5 submissions · 5 cleared · 2005-2019

REGULATORY CONSULTANT

Consulting firm	**Enmed Lntemtional, Inc.**
Contact	Louise Focht

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov