FDA 510(k) Premarket Notification

K211592 Avanti Orthopaedics Ulnar Shortening System

CLEARED

Jul 16, 2021
53 days to decision

K211592 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k211592/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	May 24, 2021
Decision date	Jul 16, 2021
Days to decision	53 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Avanti Orthopaedics, Inc.**
Location	Wilmington, DE, US
Contact	J. Doug Patterson
510(k) history	3 submissions · 3 cleared · 2019-2022

REGULATORY CONSULTANT

Consulting firm	**Secure BioMed Evaluations**
Contact	Linda Braddon

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