FDA 510(k) Premarket Notification

K220142 BRM Digitalis Spacer

CLEARED

Apr 4, 2023
441 days to decision

K220142 · Product code: **KYJ** · Orthopedic
Source: https://www.510kdatabase.net/k220142/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Finger, Constrained, Polymer (KYJ)
Date received	Jan 18, 2022
Decision date	Apr 4, 2023
Days to decision	441 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Brm Extremities Srl**
Location	Civate, IT
Contact	Andrea De Maglio
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Margeaux Rogers

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