

K220142 BRM Digitalis SpacerApr 4, 2023
441 days to decisionK220142 · 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](https://accessdata.fda.gov)

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