FDA 510(k) Premarket Notification

K203634 BioPoly Great Toe Hemiarthroplasty Implant

CLEARED

Feb 2, 2021
53 days to decision

K203634 · Product code: **KWD** · Orthopedic
Source: https://www.510kdatabase.net/k203634/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Toe, Hemi-, Phalangeal (KWD)
Date received	Dec 11, 2020
Decision date	Feb 2, 2021
Days to decision	53 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**BioPoly, LLC**
Location	Fort Wayne, IN, US
Contact	Herb Schwartz
510(k) history	3 submissions · 3 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Dave McGurl

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