FDA 510(k) Premarket Notification

K234123 Easi-Vue® embolic microspheres System

CLEARED

Feb 13, 2024
47 days to decision

K234123 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k234123/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Dec 28, 2023
Decision date	Feb 13, 2024
Days to decision	47 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Abk Biomedical, Inc.**
Location	Halifax, CA
Contact	Brandi Woods
510(k) history	2 submissions · 2 cleared · 2022-2024