FDA 510(k) Premarket Notification

K213200 Solus Gold Embolization Device

CLEARED

Mar 21, 2022
173 days to decision

K213200 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k213200/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Sep 29, 2021
Decision date	Mar 21, 2022
Days to decision	173 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Artio Medical, Inc.**
Location	Menlo Park, CA, US
Contact	Erdie De Peralta
510(k) history	1 submissions · 1 cleared · 2022-2022