FDA 510(k) Premarket Notification

K222017 Biotres

CLEARED

Jul 28, 2022
20 days to decision

K222017 · Product code: **MWJ** · Cardiovascular
Source: https://www.510kdatabase.net/k222017/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrocardiograph, Ambulatory (without Analysis) (MWJ)
Date received	Jul 8, 2022
Decision date	Jul 28, 2022
Days to decision	20 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biotricity**
Location	Redwood City, CA, US
Contact	Spencer LaDow
510(k) history	3 submissions · 3 cleared · 2020-2022