FDA 510(k) Premarket Notification

K221700 AutoPulse NXT Resuscitation System

CLEARED

Mar 9, 2023
269 days to decision

K221700 · Product code: **DRM** · Cardiovascular
Source: https://www.510kdatabase.net/k221700/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Compressor, Cardiac, External (DRM)
Date received	Jun 13, 2022
Decision date	Mar 9, 2023
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zoll Circulation, Inc.**
Location	San Jose, CA, US
Contact	Brian Robey
510(k) history	8 submissions · 3 cleared · 2015-2025