FDA 510(k) Premarket Notification

K211289 RMU-2000 Automated Chest Compression System

CLEARED

Nov 9, 2021
195 days to decision

K211289 · Product code: **DRM** · Cardiovascular
Source: https://www.510kdatabase.net/k211289/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Compressor, Cardiac, External (DRM)
Date received	Apr 28, 2021
Decision date	Nov 9, 2021
Days to decision	195 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Defibtech, LLC**
Location	Guilford, CT, US
Contact	Allison Bohren
510(k) history	9 submissions · 8 cleared · 2002-2021

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k211289/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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