FDA 510(k) Premarket Notification

K121853 DDU-2400/2450 SEMIAUTOMATIC EXTERNAL DEFIBRILLATOR AND ACCESSORIES

CLEARED

Dec 13, 2012
171 days to decision

K121853 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k121853/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Jun 25, 2012
Decision date	Dec 13, 2012
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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