

K133441 ONESTEP CPR II MULTI-FUNCTION ELECTRODEOct 10, 2014
332 days to decisionK133441 · Product code: **MKJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k133441/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Nov 12, 2013
Decision date	Oct 10, 2014
Days to decision	332 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Detek, Inc.
Location	Mansfield, MA, US
Contact	SHANNON DUHAMEL
510(k) history	17 submissions · 17 cleared · 1985-2015

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