

K100565 DURA PADZ (REUSABLE ELECTRODE), DURA PADZ GEL (DISPOSABLE HYDROGEL) MODEL 8900-0300, 8900-0325Nov 16, 2010
260 days to decisionK100565 · Product code: **MKJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k100565/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Mar 1, 2010
Decision date	Nov 16, 2010
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100565/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 4, 2026