

K123916 PSA SERIESApr 9, 2013
111 days to decisionK123916 · Product code: **DTE** · Cardiovascular
Source: <https://www.510kdatabase.net/k123916/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Pulse-generator, Pacemaker, External (DTE)
Date received	Dec 19, 2012
Decision date	Apr 9, 2013
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osyka Medical, Inc.
Location	La Jolla, CA, US
Contact	MARKUS OSYPKA
510(k) history	7 submissions · 6 cleared · 2002-2013

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