

K002089 ROSETTA-LT/ROSETTA-RXNov 21, 2000
133 days to decisionK002089 · Product code: **DRG** · Cardiovascular
Source: <https://www.510kdatabase.net/k002089/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Jul 11, 2000
Decision date	Nov 21, 2000
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	General Devices
Location	Bergenfield, NJ, US
Contact	MICHAEL SMITH
510(k) history	13 submissions · 13 cleared · 1983-2002

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