

K013533 EMS TELEMEDICINE OPTION (FOR GEMS SERIES 4000)

Jan 18, 2002
87 days to decision

K013533 · Product code: **DRG** · Cardiovascular
Source: <https://www.510kdatabase.net/k013533/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Oct 23, 2001
Decision date	Jan 18, 2002
Days to decision	87 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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Device record: <https://www.510kdatabase.net/k013533/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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