

K921929 GEMSCOM SERIES 300 12-LEAD ECG (12-LEAD OPTION)

Sep 18, 1992
147 days to decision

K921929 · Product code: **DXH** · Cardiovascular
Source: <https://www.510kdatabase.net/k921929/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Apr 24, 1992
Decision date	Sep 18, 1992
Days to decision	147 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k921929/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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