FDA 510(k) Premarket Notification

K935839 GEMSCOM SERIES 5000,

CLEARED

Nov 10, 1994
338 days to decision

K935839 · Product code: **DRG** · Cardiovascular
Source: https://www.510kdatabase.net/k935839/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Dec 7, 1993
Decision date	Nov 10, 1994
Days to decision	338 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