

K011597 SMARTMONITOR 2, MODEL 4000Jan 11, 2002
232 days to decisionK011597 · Product code: **FLS** · Anesthesiology
Source: <https://www.510kdatabase.net/k011597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Monitor, Apnea, Facility Use (FLS)
Date received	May 24, 2001
Decision date	Jan 11, 2002
Days to decision	232 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Respironics Georgia, Inc.
Location	Marietta, GA, US
Contact	BETSY CORTELLONI
510(k) history	2 submissions · 2 cleared · 2001-2002

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