

K020607 SLEEPFLO, MODEL 101501Aug 30, 2002
186 days to decisionK020607 · Product code: **MNR** · Anesthesiology
Source: <https://www.510kdatabase.net/k020607/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Feb 25, 2002
Decision date	Aug 30, 2002
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomec, Inc.
Location	Cleveland, OH, US
Contact	TRACEY H WIELINSKI
510(k) history	1 submissions · 1 cleared · 2002-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k020607/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026