

K160499 Apnea Risk Evaluation System (ARES), Model 620Apr 24, 2017
426 days to decisionK160499 · Product code: **MNR** · Anesthesiology
Source: <https://www.510kdatabase.net/k160499/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Feb 23, 2016
Decision date	Apr 24, 2017
Days to decision	426 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Watermark Medical
Location	Brookfield, WI, US
Contact	Frank Katarow
510(k) history	3 submissions · 3 cleared · 2012-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160499/> 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 24, 2026