

**K200654 Rubicon SA System**Jul 22, 2020  
132 days to decisionK200654 · Product code: **MNR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k200654/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Mar 12, 2020
Decision date	Jul 22, 2020
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Dymedix Diagnostics, Inc.</b>
Location	Shoreview, MN, US
Contact	Jim Moore
510(k) history	2 submissions · 2 cleared · 2020-2020

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Dymedix Diagnostics, Inc. C/O Promedic, LLC</b>
Contact	Paul Dryden

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200654/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026