FDA 510(k) Premarket Notification

K200654 Rubicon SA System

CLEARED

Jul 22, 2020
132 days to decision

K200654 · 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	**Dymedix Diagnostics, Inc.**
Location	Shoreview, MN, US
Contact	Jim Moore
510(k) history	2 submissions · 2 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Dymedix Diagnostics, Inc. C/O Promedic, LLC**
Contact	Paul Dryden

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