

K173793 XactTrace Single Use Respiratory Effort Belt SystemMar 1, 2019
442 days to decisionK173793 · Product code: **MNR** · AnesthesiologySource: <https://www.510kdatabase.net/k173793/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Dec 14, 2017
Decision date	Mar 1, 2019
Days to decision	442 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Embla Systems
Location	Thornton, CO, US
Contact	Sanjay Mehta
510(k) history	8 submissions · 8 cleared · 2011-2019

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