

**K180001 Disposable BreathSensor Adult, Disposable BreathSensor Small Adult / Child, Disposable BreathSensor Premie, Disposable BreathSensor Infant**

Sep 27, 2019  
633 days to decision

K180001 · Product code: **MNR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k180001/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Jan 2, 2018
Decision date	Sep 27, 2019
Days to decision	633 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k180001/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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