

**K220012 BresDX1**Dec 21, 2022  
351 days to decisionK220012 · Product code: **MNR** · AnesthesiologySource: <https://www.510kdatabase.net/k220012/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Jan 4, 2022
Decision date	Dec 21, 2022
Days to decision	351 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bresotec, Inc.</b>
Location	Toronto, CA
Contact	Esther Sur
510(k) history	1 submissions · 1 cleared · 2022-2022

**CLINICAL EVIDENCE - NCT04897399**

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**[Trial of device that is not approved or cleared by the U.S. FDA]**

Status	Withheld - <i>No results published to ClinicalTrials.gov</i>
Sponsor	[Redacted]

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT04897399](https://clinicaltrials.gov/study/NCT04897399)

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220012/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)), ClinicalTrials.gov (U.S. National Library of Medicine).  
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