

**K222950 AcuPebble OX100**Feb 3, 2023  
129 days to decisionK222950 · Product code: **MNR** · AnesthesiologySource: <https://www.510kdatabase.net/k222950/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Sep 27, 2022
Decision date	Feb 3, 2023
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Acurable Limited</b>
Location	London, GB
Contact	Esther Rodriguez-Villegas
510(k) history	3 submissions · 3 cleared · 2021-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222950/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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