

**K251448 FL-10000U Respiratory Humidifier**Jan 16, 2026  
252 days to decisionK251448 · Product code: **BTT** · Anesthesiology  
Source: <https://www.510kdatabase.net/k251448/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	May 9, 2025
Decision date	Jan 16, 2026
Days to decision	252 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Flexicare Medical Limited.</b>
Location	Mountain Ash, GB
Contact	Rebecca Funston
510(k) history	8 submissions · 8 cleared · 2016-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251448/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026