

**K161314 FLEXICARE FL-9000U RESPIRATORY HUMIDIFIER
BASE**Jul 6, 2016
56 days to decisionK161314 · Product code: **BTT** · Anesthesiology
Source: <https://www.510kdatabase.net/k161314/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	May 11, 2016
Decision date	Jul 6, 2016
Days to decision	56 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Flexicare Medical Limited.
Location	Mountain Ash, GB
Contact	JOEL BIDDLE
510(k) history	8 submissions · 8 cleared · 2016-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161314/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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