

K160540 FLEXICARE NEONATAL HEATED WIRE BREATHING SYSTEMJun 23, 2016
118 days to decisionK160540 · Product code: **BZE** · Anesthesiology
Source: <https://www.510kdatabase.net/k160540/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heater, Breathing System W/wo Controller (not Humidifier Or Nebulizer (BZE))
Date received	Feb 26, 2016
Decision date	Jun 23, 2016
Days to decision	118 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

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