

**K201666 SINGLE USE MANOMETER**Nov 13, 2020  
147 days to decisionK201666 · Product code: **CAP** · Anesthesiology  
Source: <https://www.510kdatabase.net/k201666/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Airway Pressure (includes Gauge And/or Alarm) (CAP)
Date received	Jun 19, 2020
Decision date	Nov 13, 2020
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Flexicare Medical Limited.</b>
Location	Mountain Ash, GB
Contact	Joel Biddle
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/k201666/> 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 24, 2026