

**K180902 MediPines Gas Exchange Monitor (GEM), Accessory  
Mouthpiece Disposable Assembly**Jan 11, 2019  
280 days to decisionK180902 · Product code: **CCK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k180902/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Apr 6, 2018
Decision date	Jan 11, 2019
Days to decision	280 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medipines Corporation</b>
Location	Anaheim Hill, CA, US
Contact	Steve Lee
510(k) history	1 submissions · 1 cleared · 2019-2019

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180902/> 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 June 28, 2026