

**K173108 Smoklean**May 18, 2018  
231 days to decisionK173108 · Product code: **FYD** · General HospitalSource: <https://www.510kdatabase.net/k173108/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Exhaust, Surgical (FYD)
Date received	Sep 29, 2017
Decision date	May 18, 2018
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sejong Medical Co., Ltd.</b>
Location	Paju-Si, KR
Contact	Yoojung Choi
510(k) history	7 submissions · 7 cleared · 2017-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173108/> 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 26, 2026