

**K210279 Enbio S**Oct 29, 2021  
270 days to decisionK210279 · Product code: **FLE** · General HospitalSource: <https://www.510kdatabase.net/k210279/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Steam (FLE)
Date received	Feb 1, 2021
Decision date	Oct 29, 2021
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Enbio Group AG</b>
Location	Oensingen, CH
Contact	Lukasz Rogowski
510(k) history	3 submissions · 3 cleared · 2021-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210279/> 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