

**K260254 Enbio PRO**Feb 26, 2026  
30 days to decisionK260254 · Product code: **FLE** · General Hospital  
Source: <https://www.510kdatabase.net/k260254/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Steam (FLE)
Date received	Jan 27, 2026
Decision date	Feb 26, 2026
Days to decision	30 days
Third-party review	Yes
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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260254/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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