

K213991 Enbio SFeb 22, 2022
63 days to decisionK213991 · Product code: **FLE** · General HospitalSource: <https://www.510kdatabase.net/k213991/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sterilizer, Steam (FLE)
Date received	Dec 21, 2021
Decision date	Feb 22, 2022
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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