

K223858 Lexa MINI (RIS-303, RIS-305)May 5, 2023
133 days to decisionK223858 · Product code: **FLE** · General Hospital
Source: <https://www.510kdatabase.net/k223858/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Steam (FLE)
Date received	Dec 23, 2022
Decision date	May 5, 2023
Days to decision	133 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	W&H Sterilization S.R.L.
Location	Brusaporto, IT
Contact	Paola Zampino
510(k) history	4 submissions · 4 cleared · 2018-2024

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