

K172825 MN-111May 30, 2018
254 days to decisionK172825 · Product code: **FLE** · General Hospital
Source: <https://www.510kdatabase.net/k172825/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Steam (FLE)
Date received	Sep 18, 2017
Decision date	May 30, 2018
Days to decision	254 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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