

K213080 T-Edge 10, T-Edge 11Jan 4, 2022
103 days to decisionK213080 · Product code: **FLE** · General Hospital
Source: <https://www.510kdatabase.net/k213080/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Steam (FLE)
Date received	Sep 23, 2021
Decision date	Jan 4, 2022
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tuttnauer , Ltd.
Location	Beit Shemesh, IL
Contact	Robert Basile
510(k) history	4 submissions · 4 cleared · 2019-2022

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