FDA 510(k) Premarket Notification

K213758 Lexa PLUS RIS-311

CLEARED

Aug 19, 2022
262 days to decision

K213758 · Product code: **FLE** · General Hospital
Source: https://www.510kdatabase.net/k213758/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Steam (FLE)
Date received	Nov 30, 2021
Decision date	Aug 19, 2022
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	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

REGULATORY CONSULTANT

Consulting firm	**Blackwell Device Consulting**
Contact	Angela Blackwell

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