

K250061 Celerity IncubatorFeb 6, 2025
27 days to decisionK250061 · Product code: **FRC** · General HospitalSource: <https://www.510kdatabase.net/k250061/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Jan 10, 2025
Decision date	Feb 6, 2025
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	STERIS Corporation
Location	Mentor, OH, US
Contact	Karly Eitzman
510(k) history	204 submissions · 202 cleared · 1997-2026

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