

K233681 ConFirm 20 Minute IncubatorDec 15, 2023
29 days to decisionK233681 · Product code: **FRC** · General HospitalSource: <https://www.510kdatabase.net/k233681/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Nov 16, 2023
Decision date	Dec 15, 2023
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233681/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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