

K190297 Celerity HP IncubatorMay 14, 2019
92 days to decisionK190297 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k190297/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Feb 11, 2019
Decision date	May 14, 2019
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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