

K192025 STERRAD VELOCITY Biological Indicator/Process Challenge Device and Reader

Jan 23, 2020
178 days to decision

K192025 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k192025/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Jul 29, 2019
Decision date	Jan 23, 2020
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Advanced Sterilization Products (Asp)
Location	Irvin, CA, US
Contact	Elsie Kim
510(k) history	5 submissions · 5 cleared · 2016-2020

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k192025/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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