

K192980 EOGas 4 Endo-SteriTestNov 12, 2020
385 days to decisionK192980 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k192980/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Oct 24, 2019
Decision date	Nov 12, 2020
Days to decision	385 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Andersen Sterilizers, Inc.
Location	Haw River, NC, US
Contact	William K. Andersen
510(k) history	19 submissions · 19 cleared · 2015-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192980/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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