

K190104 SYSTEM 1E Liquid Chemical Sterilant Processing System, SYSTEM 1 Endo Liquid Chemical Sterilant Processing System

Mar 22, 2019
59 days to decision

K190104 · Product code: **MED** · General Hospital
Source: <https://www.510kdatabase.net/k190104/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sterilant, Medical Devices (MED)
Date received	Jan 22, 2019
Decision date	Mar 22, 2019
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Steris Corporations
Location	Mentor, OH, US
Contact	Jennifer Nalepka
510(k) history	7 submissions · 7 cleared · 2018-2021

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k190104/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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