FDA 510(k) Premarket Notification

CLEARED

K190103 V-PRO maX 2 Low Temperature Sterilization System, V-PRO maX Low Temperature Sterilization System, V-PRO 1 Plus Low Temperature Sterilization System, V-PRO 1 Low Temperature Sterilization System

Apr 5, 2019
73 days to decision

K190103 · Product code: **MLR** · General Hospital
Source: https://www.510kdatabase.net/k190103/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sterilizer, Chemical (MLR)
Date received	Jan 22, 2019
Decision date	Apr 5, 2019
Days to decision	73 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