FDA 510(k) Premarket Notification

CLEARED

K182568 V-PRO s2 Low Temperature Sterilization System, V-PRO 60 Low Temperature Sterilization System

Jan 3, 2019
107 days to decision

K182568 · Product code: **MLR** · General Hospital
Source: https://www.510kdatabase.net/k182568/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Chemical (MLR)
Date received	Sep 18, 2018
Decision date	Jan 3, 2019
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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