FDA 510(k) Premarket Notification

CLEARED

K182827 SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model 6900

Jan 31, 2019
118 days to decision

K182827 · Product code: **MED** · General Hospital
Source: https://www.510kdatabase.net/k182827/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilant, Medical Devices (MED)
Date received	Oct 5, 2018
Decision date	Jan 31, 2019
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**STERIS Corporation**
Location	Mentor, OH, US
Contact	Marcia L. Benedict
510(k) history	204 submissions · 202 cleared · 1997-2026