FDA 510(k) Premarket Notification

K170956 SYSTEM 1E Liquid Chemical Sterilant Processing System

CLEARED

Sep 22, 2017
175 days to decision

K170956 · Product code: **MED** · General Hospital
Source: https://www.510kdatabase.net/k170956/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilant, Medical Devices (MED)
Date received	Mar 31, 2017
Decision date	Sep 22, 2017
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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