FDA 510(k) Premarket Notification

K233762 SteroScope® Sterilization Technology System

CLEARED

Jun 27, 2024
216 days to decision

K233762 · Product code: **MLR** · General Hospital
Source: https://www.510kdatabase.net/k233762/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Chemical (MLR)
Date received	Nov 24, 2023
Decision date	Jun 27, 2024
Days to decision	216 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ideate Medical, Inc.**
Location	St. Louis, MO, US
Contact	William Wong
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Corrigan Regulatory Consulting**
Contact	Kevin Corrigan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov