FDA 510(k) Premarket Notification

K080420 RESERT XL HLD HIGH LEVEL DISINFECTANT

CLEARED

Sep 2, 2008
200 days to decision

K080420 · Product code: **MED** · General Hospital
Source: https://www.510kdatabase.net/k080420/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilant, Medical Devices (MED)
Date received	Feb 15, 2008
Decision date	Sep 2, 2008
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**STERIS Corporation**
Location	Mentor, OH, US
Contact	JOHN R SCOVILLE JR.
510(k) history	204 submissions · 202 cleared · 1997-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k080420/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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