FDA 510(k) Premarket Notification

K231500 Vis-U-All Low Temperature Sterilization Pouches

CLEARED

Aug 7, 2023
75 days to decision

K231500 · Product code: **FRG** · General Hospital
Source: https://www.510kdatabase.net/k231500/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	May 24, 2023
Decision date	Aug 7, 2023
Days to decision	75 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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