

K183297 Vis-U-All Low Temperature Sterilization Pouch/TubingJan 3, 2019
37 days to decisionK183297 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k183297/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Nov 27, 2018
Decision date	Jan 3, 2019
Days to decision	37 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

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