

K183401 Vis-U-All Low Temperature Sterilization Pouch/TubingMar 1, 2019
84 days to decisionK183401 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k183401/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Dec 7, 2018
Decision date	Mar 1, 2019
Days to decision	84 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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