

**K200336 Tyvek Sterilization Pouches with Chevron Seal**Nov 12, 2020  
275 days to decisionK200336 · Product code: **FRG** · General Hospital  
Source: <https://www.510kdatabase.net/k200336/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Feb 11, 2020
Decision date	Nov 12, 2020
Days to decision	275 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Andersen Sterilizers, Inc.</b>
Location	Haw River, NC, US
Contact	William K Andersen
510(k) history	19 submissions · 19 cleared · 2015-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200336/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 27, 2026