

**K180672 Sterilization Pouch/Roll Made with Tyvek**Jun 6, 2018  
84 days to decisionK180672 · Product code: **FRG** · General Hospital  
Source: <https://www.510kdatabase.net/k180672/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Wrap, Sterilization (FRG)
Date received	Mar 14, 2018
Decision date	Jun 6, 2018
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sigma Medical Supplies Corporation</b>
Location	New Taipei City, TW
Contact	Mason Huang
510(k) history	2 submissions · 2 cleared · 2018-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180672/> 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