

**K202462 SIGMA Sterilization Pouch and Roll**Apr 23, 2021  
239 days to decisionK202462 · Product code: **FRG** · General Hospital  
Source: <https://www.510kdatabase.net/k202462/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Wrap, Sterilization (FRG)
Date received	Aug 27, 2020
Decision date	Apr 23, 2021
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Sen MU Technology Co., Ltd.</b>
Contact	Uta Shih

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202462/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026