

**K102158 SIGMA STERILIZATION POUCH & ROLL**Aug 2, 2011  
368 days to decisionK102158 · Product code: **FRG** · General Hospital  
Source: <https://www.510kdatabase.net/k102158/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Jul 30, 2010
Decision date	Aug 2, 2011
Days to decision	368 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sigma Medical Supplies Corp.</b>
Location	Kaohsiung, TW
Contact	UTA SHIH
510(k) history	3 submissions · 3 cleared · 2011-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k102158/> 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 30, 2026