

K133838 STERILIZATION POUCH/ROLL MADE WITH TYVEKMar 11, 2015
448 days to decisionK133838 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k133838/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Dec 18, 2013
Decision date	Mar 11, 2015
Days to decision	448 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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