

K180661 SIGMA Sterilization Pouch and RollJun 5, 2018
83 days to decisionK180661 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k180661/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Wrap, Sterilization (FRG)
Date received	Mar 14, 2018
Decision date	Jun 5, 2018
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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