

**K162362 PMSSteripack Flat Sterilization Pouch (FP) and Roll (FL) with Chemical Indicator**Oct 13, 2017  
416 days to decisionK162362 · Product code: **FRG** · General Hospital  
Source: <https://www.510kdatabase.net/k162362/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Aug 23, 2016
Decision date	Oct 13, 2017
Days to decision	416 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pms Tibbi Cihazlar Teknolojisi San VE Tic AS</b>
Location	Mersin, TR
Contact	DERYA DIKICI
510(k) history	1 submissions · 1 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162362/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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