

K181957 Heat Sealing Sterilization Pouch Flat, Heat Sealing Sterilization Pouch Gusseted, Heat Sealing Sterilization Pouch Roll Flat, Heat Sealing Sterilization Pouch Roll GussetedJul 9, 2019
351 days to decisionK181957 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k181957/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Jul 23, 2018
Decision date	Jul 9, 2019
Days to decision	351 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tianchang Jiarui Packaging Material Co., Ltd.
Location	Tianchang, CN
Contact	Zhang Ruiqing
510(k) history	2 submissions · 2 cleared · 2017-2019

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray Wang

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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