

K193561 Disposable Medical Device Self-seal Sterilization Pouch, Disposable Medical Device Sterilization Reel PouchApr 15, 2020
114 days to decisionK193561 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k193561/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wrap, Sterilization (FRG)
Date received	Dec 23, 2019
Decision date	Apr 15, 2020
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Weihai Xingtai Packaging Products Co., Ltd.
Location	Weihai, CN
Contact	Miao Qifen
510(k) history	2 submissions · 2 cleared · 2019-2020

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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193561/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026