

K182184 Paper Sterilization Pouch and Roll(Sterilization Pouch Flat, Sterilization Pouch Gusseted, Sterilization Roll Flat and Sterilization Roll Gusseted)

Oct 10, 2019
423 days to decision

K182184 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k182184/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Aug 13, 2018
Decision date	Oct 10, 2019
Days to decision	423 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mdk (Shanghai) Medical Packing Co., Ltd.
Location	Shanghai, CN
Contact	Gong Yaoren
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k182184/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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