FDA 510(k) Premarket Notification

CLEARED

K153540 Safe Secure Sterilization Pouch with Steam and Ethylene Oxide Process Indicators

Aug 4, 2016
238 days to decision

K153540 · Product code: **FRG** · General Hospital
Source: https://www.510kdatabase.net/k153540/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Dec 10, 2015
Decision date	Aug 4, 2016
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Safe Secure Packaging Co., Ltd.**
Location	Shenzhen, Guangdon, CN
Contact	HOWARD JIA
510(k) history	2 submissions · 2 cleared · 2012-2016

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k153540/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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