FDA 510(k) Premarket Notification

CLEARED

Apr 30, 2008
65 days to decision

K080520 NON STERILE, POWDER FREE NITRILE EXAMINATION GLOVE, BLUE, POLYMER COATING WITH CHEMOTHERAPY CLAIM

K080520 · Product code: **LZA** · General Hospital
Source: https://www.510kdatabase.net/k080520/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 25, 2008
Decision date	Apr 30, 2008
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Siam Sempermed Corp., Ltd.**
Location	Thailand, TH
Contact	WILLIAM E HARRIS
510(k) history	37 submissions · 37 cleared · 1989-2015

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k080520/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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