

K212085 Siam NTD+ Nitrile Powder-Free Examination glovesDec 11, 2021
162 days to decisionK212085 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k212085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 2, 2021
Decision date	Dec 11, 2021
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siam Ntd Corporation Co., Ltd.
Location	Bueng Yitho Thanyaburi, TH
Contact	Taweesak Waideemaneetrakoon
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group
Contact	Taweesak Waideemaneetrakoon

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212085/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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