NATHAN TRADING CO LTD has 2 TYPES of 510(k) for Nitrile Examination Gloves – Lydus brand

TYPE 1- Transfer 510(k) from Thai Hua Holding, Number K102846

TYPE 2 – Nathan Trading's Own 510(k) Re-submitted to the FDA for Approval, Number K203191

TYPE 1 - TRANSFERRED 510(k)

Nathan Trading's FDA 510(K), number K102846, Through Transfer from Thai Hua Holding

Establishment Registration & Device Listing (fda.gov)

New Search	Back To Search Results
Proprietary Name:	Nitrile Examination Gloves, Powder-Free - LYDUS
Classification Name:	POLYMER PATIENT EXAMINATION GLOVE
Product Code:	LZA
Device Class:	1
Regulation Number:	880.6250
Medical Specialty:	General Hospital
Registered Establishment Name:	NATHAN TRADING CO., LTD.
Registered Establishment Number:	3012099156
Premarket Submission Number:	K102846
Owner/Operator:	Nathan Trading Co., Ltd.
Owner/Operator Number:	10074884
Establishment Operations:	Manufacturer

FDA Has Approved Thai Hua Holding to transfer its 510(k) number K102846 to Partner company Nathan Trading. 510(k) number K102846 is now under Nathan Trading establishment (Appendix A, Appendix B)

Device Classification Name	Polymer Patient Examination Glove
510(K) Number	K102846
Device Name	PATIENT EXAMINATION GLOVES
Applicant	THAI HUA HOLDING CO., LTD. 6324 MEETINGHOUSE WAY Alexandria, VA 22312 -1718
Applicant Contact	Kok-Kee Hon
Correspondent	THAI HUA HOLDING CO., LTD. 6324 MEETINGHOUSE WAY Alexandria, VA 22312 -1718
Correspondent Contact	Kok-Kee Hon
Regulation Number	880.6250
Classification Product Code	LZA
Date Received	09/29/2010
Decision Date	03/17/2011
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Appendix A

Formal Letter passing the 510(k) clearance from Thai Hua Holding to Nathan Trading.

THAI HUA HOLDING COMPANY LIMITED

238/10 Ratchada-Pisek Road, Huai-Khwang, Bangkok 10310, Thailand
Tel: (66 2) 274 1673–74 Mobile: (66 081) 8373096
E-mail : Thaihuaholding@thaihua.net

14 January 2021

Prof. Dr. Chansamone Saiyasak
Managing Director / CEO
Nathan Trading Co., Ltd.
58 Moo 12 Palan Sub-District
Nathan District, Ubon Ratchathani 34170 Thailand

Dear Prof. Dr. Chansamone Saiyasak:

In order to bring up to date and activate the usage of its three medical devices, Thai Hua Holding Co., Ltd., is specifying Nathan Trading Co., Ltd., as the current 510(k) clearance holder of these following devices in order to list these devices in the FDA registration and begin its usage:

(1) Device Name: Powder-Free Nitrile Examination Gloves (Blue), K102846
(2) Device Name: Powder Free Polymer Coasted Latex Examination Gloves with Protein, K102840
(3) Device Name: Powdered Latex Examination Gloves, K102838

If you have any question, please do not hesitate to contact me.

Sincerely,

Dr. Luckchai Kittipol
(President of Thai Hua Holding Company Limited)

Appendix B

As per the below email from the FDA - Transfer of the 510(k) is complete and now listed under Nathan Trading's Establishment Registration.

Support at FDA/DICE Re:Re: Support at FDA/DICE Re:Using Another 510(k) Clearance to Support Medical [ref:_00Dd0fegA._500t0fEAjl:ref] Inbox ×

"DICE" <dice@fda.hhs.gov> <dice@fda.hhs.gov> Thu, Jan 21, 9:19 PM (6 days ago)
to me

FDA U.S. FOOD & DRUG ADMINISTRATION

Dear Dr. Saiyasak,

Thank you for contacting the Division of Industry and Consumer Education (DICE) at FDA's Center for Devices and Radiological Health (CDRH) DICE@fda.hhs.gov e-mail account.

The new and previous owners of a transferred 510(k) must update their registration and listing records with FDA according to 21 CFR 807. The new owner must register with FDA and list the acquired device. The selling company must update its registration and listings with FDA to reflect the loss of ownership, since **there may only be one 510(k) holder for a device at a time.**

While the regulation stipulates that such updates may take place within 30 days after entering into such an operation (21 CFR 807.22(a)), ideally, the new owner and the previous owner will update the listing information at the same time if there are products that are already in commercial distribution.

Additionally, it is recommended that, as part of the transfer agreement, the details regarding who is responsible for handling complaints for those products that are already in commercial distribution (prior to the transfer in ownership) should be documented and agreed upon.

Once these are completed, you can proceed with the relocation of the manufacturing process.
When relocating a manufacturing facility, you will be required to update your Registration & Listing information and follow the Quality System Regulation (21 CFR 820), where applicable. Please also visit the Updating Registration and Listing Information webpage for further information. Manufacturing relocation generally does not impact a 510(k) clearance, unless the original site was somehow integral to the original 510(k) clearance. Please work with your Quality Assurance and/or Regulatory Affairs departments to make this determination.

For additional information on mandatory Quality Systems requirements, please to the Quality System (QS) Regulation/Medical Device Good Manufacturing Practices webpage, the Quality Systems Inspections Guide, and the Quality Systems Preamble.

If we can be of further assistance, please don't hesitate to contact us (Division of Industry and Consumer Education, DICE). We are available via email at DICE@fda.hhs.gov and also by phone at (800) 638-2041 (please refer to our webpage for our hours of operation). Please direct all new email inquiries to the main email address provided. Thank you.

Sincerely

Industry Team

Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

TYPE 2 – Nathan Trading's Own 510(k)

Nathan Trading's own FDA 510(k), number K203191, is being obtained through the process of direct application or submission to the FDA. The re-submission application, number K203191 (with all the additional requirements by the FDA), is now with the FDA. It is expected that FDA 510(k), number K203191, will be approved in approximately 2 weeks (or by February 12, 2021) (Appendix C, Appendix D) , (Appendix E)

Appendix C

FDA U.S. FOOD & DRUG ADMINISTRATION

K203191
Nathan Trading Co., Ltd
Trade/Device Name: LYDUS Nitrite Examination Gloves, Powder Free
Contact Name: Abdel Halim

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K203191 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K203191 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at https://www.fda.gov/media/83522/download for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" issued

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Appendix E

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

1/28/2021

Abdel B. Halim, President
Global Quality and Regulatory Services
10 Scenic Way
Monroe, NJ 08831
UNITED STATES

Dear Abdel B. Halim:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: K203191/S001
Received: 1/28/2021
Applicant: Nathan Trading Co., Ltd
Device: LYDUS Nitrite Examination Gloves, Powder Free

We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Appendix D

NATHAN TRADING CO., LTD
58 Moo 12 Palan Sub-District, Nathan District, Ubon Ratchathani 34170 Thailand
E-mail: csaiyasak@nathantrad.com Tel.: +66 81 8789953 Web: www.nathantrad.com

October 8, 2020

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) Premarket Notification (21 CFR 880.6250)
Nathan Trading Co., Ltd.
Nitrile Examination Gloves, Powder Free

Dear Sir or Madam:

Nathan Trading Co., Ltd., hereby submits this Traditional 510(k) in accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and Title 21 CFR §807, Subpart E. The purpose of this 510(k) Premarket Notification is to request clearance for the Nathan Trading Co., LTD's LYDUS Nitrile Examination Gloves, Powder Free.

The information contained in the submission supports the substantial equivalence* of the LYDUS Nitrile Examination Gloves, Powder Free.

There have been no prior submissions to seek clearance for the components subject of this Traditional 510(k) submission.

General Information	
Trade Name	LYDUS Nitrile Examination Gloves, Powder Free K203191
Common Name	Exam Gloves
Predicate 510(k)	Blue Nitrile Examination Gloves Powder Free K192333
Product Code	LZA
Device Classification Nam	Patient Examination Gloves
Device Class	Class I
Device Classification Number	21 CFR 880.6250
Review Panel	General Hospital & Personal Use
Manufacturer	NATHAN TRADING CO., LTD.
Registration/FEI #	3012099156