June 22, 2022

Thanh Cong Pharmaceutical and Trading Company Limited
℅ Manoj Zacharias
US Agent
Liberty Management Group Limited
75 Executive Drive, Suite 114
Aurora, Illinois 60504

Re: K221185
Trade/Device Name: TC Gloves Powder Free Latex Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYY
Dated: March 29, 2022
Received: April 25, 2022

Dear Manoj Zacharias:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bifeng Qian, M.D., Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221185

Device Name
TC Gloves Powder Free Latex Examination Gloves

Indications for Use *(Describe)*
TC Gloves Powder Free Latex Examination Gloves is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY K221185

[AS REQUIRED BY 21CFR807.92]

I. SUBMITTER DETAILS

510(k) Owner's Name	THANH CONG PHARMACEUTICAL AND TRADING COMPANY LIMITED
Address	KM 6+ 200 National Road No.38, Hap Linh, Bac Ninh City, Bac Ninh province, Vietnam
Contact person	Ms. Nguyễn Thị Tú Anh
Contact Designation	Director of Production
Contact Phone Number	098 171 2992
Contact Email	tuanhnguyentcpharma@gmail.com
Date of Summary Prepared	07-04-2022

II. DEVICE DETAILS

Brand Name	TC Gloves
Device Common Name	Powder-Free Latex Examination Gloves
Device Classification name	Non-powdered patient examination glove
Regulation Number	21 CFR 880.6250
Class	I
Product Code	LYY

III. PREDICATE DEVICE DETAILS

Predicate Device Name	Palm Care Latex Examination Powder Free Gloves
510(k) Number	K202377
Regulation Number	21 CFR 880.6250
Class	I
Product Code	LYY

IV. DEVICE DESCRIPTION

TC Gloves Powder Free Latex Examination Gloves is a Class I device bearing the product code LYY (21CFR 880.6250). They meet all the current specifications listed under the ASTM D3578 - 19, Standard Specification for Rubber Examination Gloves. They are made from natural rubber latex. These gloves are white in color having Finger Texture / Ambidextrous and are powder free. The product is non-sterile.

V. INDICATION FOR USE

TC Gloves Powder-Free Latex Examination Gloves is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1: General Comparison

Sl. No	Features compared	Proposed Device	Predicate Device	Result
General Information				
1.	510(k) Number	K221185	K202377	-
2.	Manufacturer	Thanh Cong Pharmaceutical And Trading Company Limited	Hi-Care Thai Gloves Co. Ltd.	-
3.	Classification	I	I	Same
4.	Regulation number	21 CFR 880.6250	21 CFR 880.6250	Same
5.	Product Code	LYY	LYY	Same
6.	Indication For Use	TC Gloves Powder-Free Latex Examination Gloves are disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner.	Palm Care Latex Examination Powder Free Gloves are disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner.	Same
7.	Material	Latex	Latex	Same
8.	Color	White	Natural (No color is added)	Different-1
9.	Texture	Finger Texture	Finger texture	Same
10.	Ambidextrous	Yes	Yes	Same
11.	Size	S, M, L, XL	XS, S, M, L	Similar-1

Sl. No	Features compared		Proposed Device	Predicate Device	Result
12.	OTC Use		Yes	Yes	Same
13.	Reusability		Single use	Single use	Same
14.	Sterility		Non- sterile	Non- sterile	Same
15.	Dimensions		Length Min 230 mm Width Min 95+/-10 mm (for medium size)	Length Min 230 m Width Min 95+/-10 Mm (for medium size)	Same
16.	Thickness		Palm min 0.08 mm Finger min 0.08 mm	Palm min 0.08 mm Finger min 0.08 mm	Same
17.	Physical Properties		<u>Before Aging</u> Tensile Strength min 18 Mpa Ultimate Elongation Min 650% <u>After Aging</u> Tensile Strength min 14 Mpa Ultimate Elongation Min 500%	<u>Before Aging</u> Tensile Strength min 18 Mpa Ultimate Elongation Min 650% <u>After Aging</u> Tensile Strength min 14 Mpa Ultimate Elongation Min 500%	Same
18.	Detection of Holes		Passes AQL 2.5	Passes AQL 1.5	Different-2
19.	Powder Free Residue		≤2 mg/glove	≤2 mg/glove	same
20.	Extractable Protein Testing		200 µg/ dm^2 max	200 µg/ dm^2 max	same
21.	Biocompatibility Study	Invitro Cytotoxicity	Under the conditions of the study, cytotoxic to L-929 cells. Additional Testing was performed to determine if this was a systemic toxicity concern.	Under the conditions of the study, non-cytotoxic.	Different-3
		Skin Sensitization	Under the conditions of the study not a sensitizer	Under the conditions of the study not a sensitizer	same
		Skin Irritation	Under the condition of study not an irritant	Under the condition of study not an irritant	same
		Acute Systemic Toxicity	Under the condition of study, the device extracts do not pose a systemic toxicity.	Under the condition of study, the device extracts do not pose a systemic toxicity.	same
		Material Mediated Pyrogenicity	Under the conditions of the study, the device did not demonstrate a material mediated Pyrogenicity response.	Under the conditions of the study, the device did not demonstrate a material mediated Pyrogenicity response.	same

There are no significant differences between the two products and are identical in terms of intended use, materials, design, manufacturing methods. Both devices met the performance standards.

VII. PERFORMANCE DATA

A. Non- Clinical Data

Performance Tests

TC Gloves Powder-Free Latex Examination Gloves is subjected to the following performance tests according to the requirements of Guidance for Industry and FDA Staff - Medical Glove Guidance Manual and found to be safe and efficient with respect to its intended use:

- Dimension
- Physical property
- Barrier property tests
  - Detection of Holes in Medical Gloves
- Powder Free Residue
- Extractable protein testing

Table 2: Performance Testing Summary

<table>
<tr><th>Sl No.</th><th>Tests</th><th colspan="3">Proposed Device actual Data</th><th colspan="3">Acceptance Criteria</th><th>Result</th></tr>
<tr><td rowspan="13">1.</td><td rowspan="13"><u>Dimension</u>

Length, Width and Thickness
ASTM D3578 - 19, Standard Specification for Rubber Examination Gloves</td><td>Size</td><td>Length</td><td>Width</td><td>Size</td><td>Length</td><td>Width</td><td rowspan="13">Pass</td></tr>
<tr><td>S</td><td>240.9mm</td><td>85mm</td><td>S</td><td rowspan="4">230mm min</td><td>80mm ±10</td></tr>
<tr><td>M</td><td>240.6mm</td><td>95.8mm</td><td>M</td><td>95mm ±10</td></tr>
<tr><td>L</td><td>240.7mm</td><td>104.5mm</td><td>L</td><td>111mm ±10</td></tr>
<tr><td>XL</td><td>240.3mm</td><td>113.5mm</td><td>XL</td><td>120mm ±10</td></tr>
<tr><td colspan="3">Thickness</td><td colspan="3">Thickness</td></tr>
<tr><td>Size</td><td>Palm</td><td>Finger</td><td>Size</td><td>Palm</td><td>Finger</td></tr>
<tr><td>S</td><td>0.13mm</td><td>0.15mm</td><td>S</td><td rowspan="4">0.08 mm min</td><td rowspan="4">0.08 mm min</td></tr>
<tr><td>M</td><td>0.14mm</td><td>0.15mm</td><td>M</td></tr>
<tr><td>L</td><td>0.14mm</td><td>0.15mm</td><td>L</td></tr>
<tr><td>XL</td><td>0.13mm</td><td>0.15mm</td><td>XL</td></tr>
<tr><td rowspan="7">2.</td><td rowspan="7"><u>Physical property</u>

Tensile strength and Ultimate Elongation
ASTM D3578 - 19, Standard Specification for Rubber Examination Gloves</td><td colspan="3">Tensile strength</td><td colspan="3">Tensile strength</td><td></td></tr>
<tr><td>Size</td><td>Before ageing</td><td>After ageing</td><td>Size</td><td>Before ageing</td><td>After ageing</td><td></td></tr>
<tr><td>S</td><td>19.9 Mpa</td><td>19.4 Mpa</td><td>S</td><td rowspan="4">18 Mpa Min for all sizes</td><td rowspan="4">14 Mpa Min for all sizes</td><td rowspan="4">Pass</td></tr>
<tr><td>M</td><td>19.8 Mpa</td><td>19.4 Mpa</td><td>M</td></tr>
<tr><td>L</td><td>20.0 Mpa</td><td>19.3 Mpa</td><td>L</td></tr>
<tr><td>XL</td><td>20.0 Mpa</td><td>19.2 Mpa</td><td>XL</td></tr>
<tr><td colspan="3">Ultimate elongation</td><td colspan="3">Ultimate elongation</td></tr>
</table>

Sl No.	Tests	Proposed Device actual Data			Acceptance Criteria			Result
		Size	**Before ageing**	**After ageing**	**Size**	**Before ageing**	**After ageing**	
		S	805.5%	790.5%	S	650% Min for all sizes	500%Min for all sizes	
		M	803.1%	794.9%	M			
		L	804.6%	791%	L			
		XL	800.9%	794.7%	XL			
3.	**Detection of Holes in Medical Gloves** ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves	**Size**	AQL 2.5		**Size**	AQL 2.5		**Pass**
		S			S			
		M			M			
		L			L			
		XL			XL			
4.	**Powder Free Residue** ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	**Size**	**Residual powder content**		**Size**	**Residual powder content**		
		S	0.31 mg		S	≤2 mg/Glove Max		**Pass**
		M	0.42 mg		M			
		L	0.57 mg		L			
		XL	0.40 mg		XL			
5.	**Extractable Protein Testing** ASTM D5712-15 Standard Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method	**Size**	**Extractable protein content**		**Size**	**Extractable protein content**		
		S	47.96 (µg/dm^2)		S	200 µg/ dm² max		**Pass**
		M	50.0 (µg/dm^2)		M			
		L	34.82 (µg/dm^2)		L			
		XL	49.27 (µg/dm^2)		XL			

B. Biocompatibility

The materials used in the TC Gloves Powder-Free Latex Examination Gloves are biocompatible based on the biocompatibility tests mentioned in the Guidance for Industry and FDA Staff - Medical Glove Guidance Manual:

- Invitro Cytotoxicity
- Skin Sensitization
- Skin Irritation
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity

These tests are performed according to ISO 10993-1:2018, Biological Evaluation of Medical Devices - Part 1, Evaluation and Testing within a Risk Management Process.

Table 3: Biocompatibility Test Summary

Sl. No	Test Performed	Proposed Device	Acceptance Criteria	Result
1.	Invitro Cytotoxicity	Under the conditions of the study, cytotoxic to L-929 cells. Additional Testing was performed to determine if this was a systemic toxicity concern	Under the conditions of the study, non-cytotoxic.	-
2.	Skin Sensitization	Under the conditions of the study not a sensitizer	Under the conditions of the study not a sensitizer	Pass
3.	Skin Irritation	Under the condition of study not an irritant	Under the condition of study not an irritant	Pass
4.	Acute Systemic Toxicity	Under the condition of study, the device extracts do not pose a systemic toxicity.	Under the condition of study, the device extracts do not pose a systemic toxicity.	Pass
5.	Material-Mediated Pyrogenicity	Under the conditions of the study, the device did not demonstrate a material mediated Pyrogenicity response.	Under the conditions of the study, the device did not demonstrate a material mediated Pyrogenicity response.	Pass

C. Clinical Test Data

Clinical study was not conducted as clinical data is not needed for TC Gloves Powder-Free Latex Examination Gloves.

VIII. CONCLUSION

The conclusion drawn from the non-clinical tests demonstrate that the subject device, TC Gloves Powder-Free Latex Examination Gloves are as safe, as effective and perform as well as or better than legally marketed predicated device in K202377.

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