K981179

# 18.0 510 (k) SUMMARY

MAY 15 1998

## 1. Submission Applicant

Name: Lovytex Sdn Bhd

Street Address: Lot 8, Jalan Suasa ,42500 Telok Panglima Garang ,

Selangor Darul Ehssn Country Malaysia

Phone No + 6-03-352 7402 FAX No + 6-03-352 7733

Contact Person: M.G. Desai

8040475 A 444401

[Registration Number, Form 2891(a)] (Device Listing Number, Form 2892)

Activity:

[ X ] Manufacturer

Applicant Lovytex Sdn Bhd

510(k) Number (if known): K981179 *

## 2. Device Particulars

Device Name: Powder-free Nitrile Examination Gloves

Trade/Proprietary Name: Lovytex Powder-free Nitrile Examination Gloves

Common Name: Powder-free Examination Gloves

Classification Name: Patient Examination Gloves

## 3. Device Classification

Device Class: Class 1

Product Code: Nitrile . 80LZA

## 4. Predicate Devices

1. Pure Advantage Powder-free Nitrile Examination Gloves ; Tillotson Healthcare Corporation
2. Safeskin Nitrile Examination Gloves ; Safeskin Corporation

## 5. Device Description

Device Class: Class 1 Product Code: Nitrile . 80LZA

## 6. Summary of Intended Use

A medical glove is worn on the hand of healthcare and similar personnel to prevent contamination between heathcare personnel and the patient.

## 7. Comparison of Characteristics to Predicate Devices

| Characteristic | Reference Document | Lovytex Device Performance | Predicate Devices * Performance |
|---|---|---|---|
| Water Leak | ASTM D 3578/FDA | Meets or Exceeds | Meets or Exceeds |
| Residual Powder | ASTM DRAFT/FDA | Meets or Exceeds | Meets or Exceeds |
| Tensile | | | |
| - Unaged | ASTM D 3578-95 | Meets or Exceeds | Meets or Exceeds |
| - Aged | ASTM D 3578-95 | Meets or Exceeds | Meets or Exceeds |

| Characteristic | Reference Document | Lovytex Device Performance | Predicate Devices * Performance |
|---|---|---|---|
| Elongation @ Break | | | |
| - Unaged | ASTM D 3578-95 | Does not meet; BUT meets ASTM D 5250 (Vinyl) | Does not meet; BUT meets ASTM D 5250 (Vinyl ) |
| - Aged | ASTM D 3578-95 | Meets or Exceeds | Meets or Exceeds |

*** 1. Tillotson Healthcare Corporation's "Pure Advantage" nitrile examination gloves**

**2. Safeskin Corporation's "Safeskin" nitrile examination gloves.**

**The "Pure Advantage" and "Safekin" gloves are however also labelled "HYPOALLERGENIC"; the subject device SHALL NOT include the "hypoallergenic" label in the packaging .**

## 7. Assessment of Non-Clinical Performance Data

The device :-

- meets or exceeds the ASTM standard or equivalent standard EXCEPT in so far as Elongation @ Break (Unaged) where it meets the requirments of ASTM 5250 applicable for Vinyl gloves .

- meets FDA pinhole requirements.

## 8. Assessment of Biocompatibility Performance Data

| | |
|---|---|
| CYTOTOXICITY | -MEM test extract was NON-TOXIC at dilution 1:4 at 24 hours.. |
| RABBIT SKIN IRRITATION | - PASSES |
| GUINEA SENSITIZATION STUDY | - PASSES |

**Lovytex Sdn. Bhd.**
(Company No. 52031-D)
Lot 8, Jalan Suasa, 42500 Telok Panglima Garang,
Kuala Langat, Selangor Darul Ehsan, Malaysia.
Tel: 603-3526711 Fax: 603-3527733

## 9. CONCLUSIONS OF NON-CLINICAL & BIOCOMPATIBILITY PERFORMANCE DATA

**The device has been carefully compared to legally marketed devices in the 510(k). The data summaries indicate that the proposed device meets or exceeds all acceptable scores for the predicate Nitrile Examination Gloves. Pursuant to 21 CFR 807.87 (j), I M.G. Desai, the Chief Executive Officer of Lovytex Sdn Bhd, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as the Chief Executive Officer of Lovytex Sdn Bhd, and in reliance thereupon, the data and information submitted in this premarket notification are truthful and accurate and that no facts material to a review of the substantial equivalence of this device have been knowingly omitted from this submission.**

(Signature)

M. G. Desai

(Typed Name)

3-27-98

(Dated)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 1998

Mr. M.G. Desai
Chief Executive Officer
Lovytex Sdn. Bhd.
(Company No. 52031-D)
Lot #8, Jalan Suasa
42500 Telok Panglima Garang,
Kuala Langat, Selangor Darul Ehsan,
MALAYSIA

Re: K981179
Trade Name: Lovytex Powder-Free Nitrile Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: March 27, 1998
Received: April 1, 1998

Dear Mr. Desai:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). You may, therefore, market the device, subject to the general controls provisions of the Act. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## 3.0 Indication For Use

**INDICATION FOR USE**

Applicant : Lovytex Sdn Bhd

510(k) Number (if known): K981179 *

Device Name: Powder-free Nitrile Examination Gloves

Indication For Use:

A medical glove is worn on the hand of healthcare and similar personnel to prevent contamination between heathcare personnel and the patient.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter X

Per 21 CFR 801.109

(optional Format 1-2-96)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981179

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