

DEC 29 1999

ATTACHMENT - I

K993450

510(k) SUMMARY

This summary of 510 (k) safety and effectiveness Information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510 (k) number is :

1. Submitter's identification : Joseph. J. E. Pereira
FITCO Dipped Products Pvt. Ltd.
14 A, Cochin Export Processing Zone,
Cochin – 682 030, Kerala, INDIA
Summary prepared on 28th September, 1999
2. Name of the Device : Latex Surgical Gloves
3. Predicate Device Information : Class 1 Latex Surgical Gloves which meets the requirements of ASTM D3577-91.
The equivalent device identified in the market is the Latex Surgical Gloves marketed by Kanam Latex Industries Pvt. Ltd., INDIA [510K NO. K904972] under brand name SURGICARE
4. Device Description : Classified by FDA's General and Plastic Surgery Device Panel as Class 1, 21 CFR 878.4460. Latex Surgical Gloves, 79 KGO and meets all requirements of ASTM standard D-3577-91.
5. Intended Use : This device is intended to be used as a single use disposable Sterile Surgical Gloves
6. Comparison to Predicate Devices : The Latex Surgical Gloves manufactured by FITCO Dipped Products Pvt. Ltd. is substantially equivalent in safety and effectiveness to the Sterile Latex Surgical Gloves marketed by Kanam Latex Industries Pvt. Ltd. India [510K NO. K904972]

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7. Discussion of Non-clinical Tests performed for determination of substantial equivalence are as follows:

The standards used for Latex Surgical Gloves production are based on ASTM-D-3577-91. All tests meet requirements of Physical and Dimensional Testing. conducted on gloves, Inspection Level S-2, AQL 2.5.

The FDA 1000 ml. Water Fill Test was also conducted with samplings of AQL 1.5, Inspection Level 1 meeting these requirements. Primary skin irritation and Skin sensitization (allergic contact dermatitis) testing was conducted with results showing, no Primary skin irritation or sensitization reactions.

There are no special labelling, claim and we do not claim our gloves as hypo allergenic on our labels.

FITCO Dipped Products Pvt. Ltd., operates in compliance with FDA's GMPs.

8. Discussion of Clinical Tests Performed:

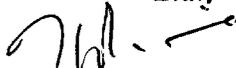
Not applicable - there is no hypoallergenic claim.

9. Conclusions:

The Latex Surgical Gloves manufactured by FITCO Dipped Products Private Limited. conform fully ASTM-D- 3577-91 standards as well as applicable 21 CFR references, and meets FDA's pinhole restrictions, bio-compatibility requirements and labelling claims as shown by data in our 510(k). There are no safety/efficacy issues or new claims from the 'Substantial equivalence' products cited.

Based on the non-clinical tests our product has demonstrated to be as safe as effective as our predicate device.

For Fitco Dipped Products Pvt. Ltd.,


JJE Pereira
Director.

Signature

Date : 28th September, 1999



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Joseph J.E. Pereira
Official Correspondent for
Fitco Dipped Products Pvt. Ltd.
Plot No. 14 - A
Cochin Export Processing Zone
Kakkanad, Cochin - 682 030
Kerala, India

Re: K993450
Trade Name: Latex Surgical Gloves , *Pre-powdered*
Regulatory Class: I
Product Code: KGO
Dated: September 28, 1999
Received: October 12, 1999

Dear Mr. Pereira:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

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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" (21 CFR 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/dsmamain.html>".

Sincerely yours,



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

Enclosure

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Attachment III

Indication for use statement

510 (K) Number (if known) 993450 : Not known

Device Name : Latex Surgical Gloves , PRE-POWDERED

Indications for use : This Surgeon's Glove is a device made of natural rubber latex intended to be worn by operating room personnel to protect a surgical wound from contamination.

Surface powder should be removed prior to undertaking operative procedures in order to minimise the risk of adverse tissue reaction.

Contents sterile until package is opened or damaged.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2-96)

Jainjurnani for Chutkan
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number 993450