SEP 1 7 2001

K012067

TTK Healthcare Limited
Biomed Division
6 Chathedral Road, Chennai – 600 086

1. 510(k) Summary

2. TTK Healthcare, Ltd.
1-B/2 MIDC Area
Chikalthana, Aurangabad
Maharashtra, India 431210

Contact: Ms. Meera Rahatkar
Telephone: 91-240-488271
Fax: 91-240-484863

June 25, 2001

3. Trade Name: CLINCARE Latex Surgical Gloves
Common Name: Surgical Gloves
Classification Name: Surgeon's Glove

4. CLINCARE Latex Surgical Gloves are class I powdered surgeon's gloves, powdered with absorbable dusting powder, and meet all the requirements of ASTM D 3577.

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6. CLINCARE Latex Surgical Gloves are sterile disposable devices intended to be worn by operating room personnel to protect a surgical wound from contamination.

7. CLINCARE latex Surgical Gloves are summarized with the following technological characteristics compared to ASTM or equivalent standards

Characteristics	Standard
Dimensions	Meets ASTM D 3577-00
Physical Properties	Meets ASTM D 3577-00, Type I
Freedom From Holes	Meets ASTM D 3577-00
Biocompatibility	
Primary Skin Irritation in Rabbits	Passes
Guinea Pig Sensitization	Passes

8. The performance test data of the non clinical tests are the same as mentioned immediately above

9. Clinical data is not needed for medical gloves or for most devices cleared by the 510(k) process.

10. It is concluded that the CLINCARE Latex Surgical Gloves are as safe, as effective, and perform as well as the glove performance standards referenced above and therefore meet:

ASTM listed standards, FDA hole requirements, and labeling claims for the product.

11. This summary will include any other information reasonably deemed necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 7 2001

TTK Healthcare Limited
C/O Mr. Eli J. Carter
Consultant
1219 Little Creek Road
Durham, North Carolina 27713

Re: K012067
Trade/Device Name: Clincare Latex Surgeon's Glove
Regulation Number: 878.4460
Regulation Name: Surgeon's Gloves
Regulatory Class: I
Product Code: KGO
Dated: June 22, 2001
Received: July 2, 2001

Dear Mr. Carter:

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. 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 (PMA), 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 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21); CFR 1000-1050.

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- 4618. 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, International and Consumer 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

Indications for Use

Applicant: TTK Healthcare Limited

510(k) Number: Not Known K012067

Device Name: Latex Surgeon's Gloves (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

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

Concurrence of DCRH Office of Device Evaluation (ODE)

Chun S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
And General Hospital Devices

510(k) Number K012067

Prescription Use _____ or Over –the- Counter _____
Per 21 CFR 801.109