APR 21 1998

K974371

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. **Submitter:** George Q. Kuo, M.D., CLK International, Inc., 28 East Broadway, 2nd Floor, New York, NY, 10002. Ph: (212) 334-3953

II. **Classification Names and Numbers:** Latex "Powder-Free" Examination Glove, 80LYY, Class I

III. **Common/Usual Name:** Latex "Powder-Free" Examination Glove

IV. **Proprietary Names:** CLK Int'l. Powder Free Latex Examination Glove

V. **Establishment Registration Number:** In Progress

VI. **Classification:** Class I

VII. **Performance Standard:**
None established under section 514.
Meets ASTM D3578 voluntary standards.

VIII. **Description of the Device:**
Product is a light and flexible glove, in standard sizes, for use in examination procedures, sold non-sterile and intended to be disposed of after use with each patient.

IX. **Substantial Equivalent:**
The CLK International glove is substantially equivalent to latex powder-free examination gloves cleared under the premarket-510(k)-process since about 1990. It complies with the required standard (see above) as do equivalent gloves.
Characteristics of the CLK Int'l latex powder-free examination gloves are compared with ASTM D3578 in Attachment I, Table I.

The "510(k) Substantial Evidence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, a disposable device intended for medical purposes that is worn on the examiner's hand(s) or finger(s) to prevent contamination between the patient and the examiner. These are the same as those of the predicate devices. These products also have the same intended uses as similar products cleared for marketing by the 510(k) process.

2. The technical characteristics for this product are the same as those for the predicate devices and those currently on the market that are prepared from rubber materials.

2. The technical characteristics for this product are the same as those for the predicate devices and those currently on the market that are prepared from rubber materials.

3. Descriptive information provided shows that the materials from which the CLK latex powder-free examination gloves made are substantially equivalent to (nearly identical with) those of similar products and are to be used for identical purposes, currently on the market. Tests show they meet the requirements of ASTM D3578 for latex examination gloves.

4. The FDA "Decision-Making Process" chart was used and appears in Attachment V.

   Data used in determining substantial equivalence include those required by ASTM D3578 and biocompatability test data as required by Int. Std ISO-10993 as modified by the FDA in the General Program Memorandum #G95-1.

   Summary of Test Data Used in Determining Equivalence:
   Physical Characteristics, before and after aging.
   Evaluation of Leakage.
   Primal Dermal Irritation.
   Maximization Sensitization (ISO)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 1998

George Q. Kuo, M.D.
President
CLK International, Incorporated
28 East Broadway, 2nd Floor
New York, New York 10002

Re: K974371
Trade Name: CLK International Powder-Free Latex Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: March 30, 1998
Received: March 31, 1998

Dear Dr. Kuo:

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

Enclosure

3.0

INDICATIONS FOR USE

Applicant: CLK International, Inc.

510(k) Number: ~~Not Applicable~~ K974371

Device Name: CLK Intl. Latex Patient Examination Glove POWDER FREE

Indications for use:

Disposable device intended for medical purposes that is worn on the examiner's hand(s) or finger(s) to prevent contamination between patient and examiner.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974371

Prescription Use ☐
Per 21 CFR 801.109

OR

Over-The-Counter ☒

(Optional Format 1-2-96)