



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 1999

Mr. Anil Taneja
General Manger
Pt. Irama Dinamika Latex
Jl. Kapten Pattimura No. 23/235
Medan 20153
INDONESIA

Re: K984449
Trade Name: Natural Rubber Pre-Powdered Colored and
Flavored Patient Examination Gloves (Pink with Tutti-
Fruti Flavor, Blue with Lemon Flavor, and Green with
Peppermint Flavor) Contains Claim of 150 mcgm or Less
of Total Water Extractable Protein Per Gram
Regulatory Class: I
Product Code: LYY
Dated: December 12, 1998
Received: January 19, 1999

Dear Mr. Taneja:

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.

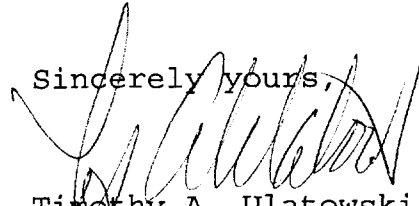
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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

**PT. IRAMA DINAMIKA LATEX**

Jl. Kapten Pattimura No. 23 / 235,

Medan - 20153, Indonesia

PHONE : (62-061) 515-834; 576-502; FAX: 553-389

E-mail : ptirama@idola.net.id

Attachment 1**Indication for Use Statement:****INDICATION FOR USE**Applicant: PT Irama Dinamika Latex510(k) Number (if known): 984449 - pendingDevice Name: Colored and Flavored Pre-powdered Latex Patient ExaminationGloves: Pink - Tutti-Frutti, Blue - lemon, Green - peppermint flavors
Contains 150mg or less of Total Water extractable protein per g

Indications For Use: A patient examination glove is disposable device intended for medical purposes that is donned by the user on the hands prevent possible contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDHR Office of Device Evaluation (ODE)

Prescription Use _____ Or Over-The-Counter ✓
Per 21 CFR 801.109
(optional Format 1-2-96)

David for Chen
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984449