



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2001

Ms. Linga Sumarta
Marketing Manager
Arista Latindo Industrial , Limited P.T.
128 Jalan Kyai Haji Muhammad
Mansyur
Jakarta Barat,
INDONESIA

Re: K013320

Trade/Device Name: Blue Latex Examination Gloves, Powder Free
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: October 2, 2001
Received: October 5, 2001

Dear Ms. Sumarta:

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.

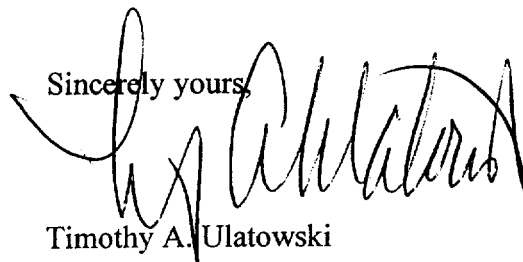
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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 Part 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



ARISTA LATINDO INDUSTRIAL LTD. P.T
GLOVE MANUFACTURER

OFFICE : J.L. KH. MOH. MANSYUR 128, JALAN KEMAS, 12010, KEMAS, MALAYSIA. MAILING ADDRESS : J.L. KH. MOH. MANSYUR 128, JALAN KEMAS, 12010, KEMAS, MALAYSIA.
TELEPHONE : (603) 638 1907-11. FAX : (603) 638 1907-12. E-MAIL : arista@arista.com.my

Section No. 3.

ATTACHMENT #2

INDICATIONS FOR USE STATEMENT

Applicant: PT. ARISTA LATINDO IND. LTD.

510(k) Number (if known): K013320 *

Device Name: Blue Latex Examination Gloves, Powder Free

Indications For Use:

A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger 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)

Prescription Use _____
Per 21 CFR 801.109

OR

Over-The-Counter X

(Optimal Format 1-2-96)

Chin S. Lin
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
Number K013320