K990841/A1

MAY 17

TERANG NUSA Sdn Bhd

510(k) Summary for NUGARD Nitrile Examination Glove

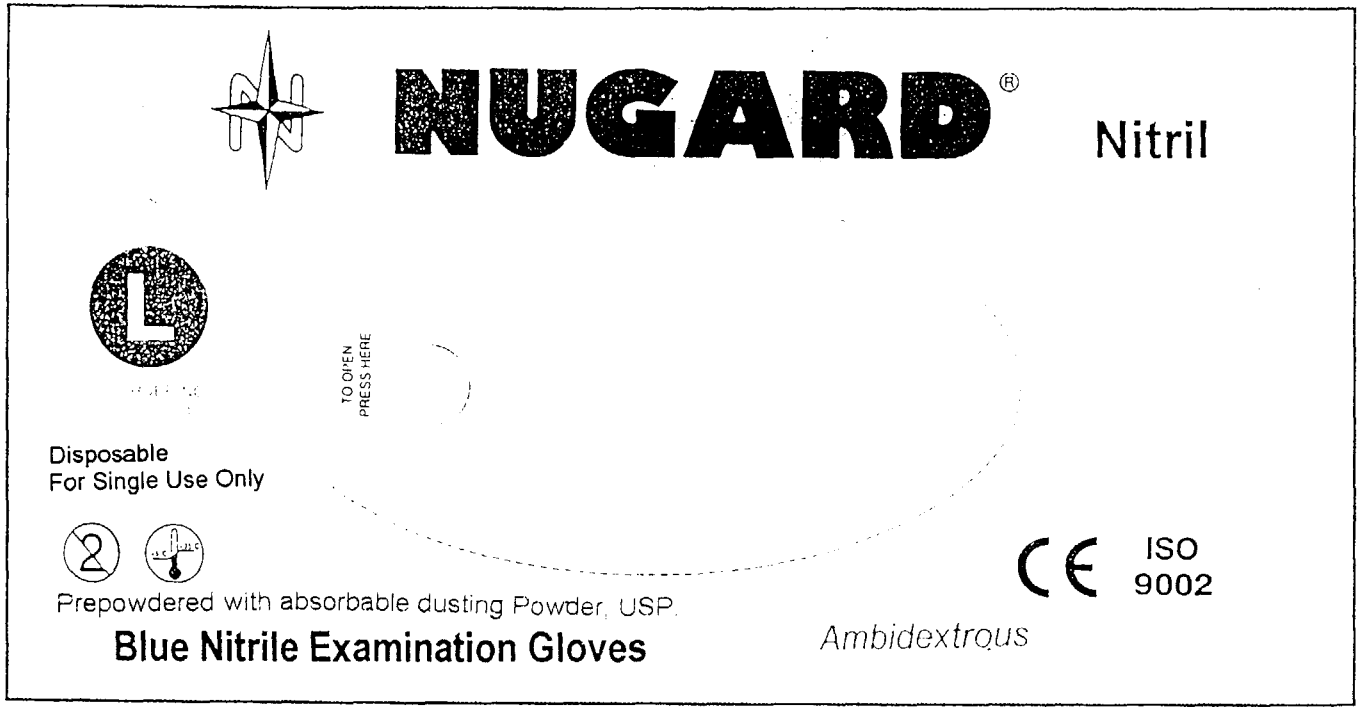
510(k) Summary

Submitter Name	Terang Nusa Sdn Bhd
Submitter Address	E4(4) , Jalan 8 Pengkalnn Chepa 2 Industrial Zone 16100 Kota Bharu, Kelantan , Malaysia.
Submitter Telephone	+60 9 7735133
Submitter Fax	+60 9 7737755
Contact Person	LOW , Chin Guan
Date of preparation	8 Mar 99
Trade Name	Nugard Nitril
Common Name	Examination Glove
Classification	Patient Examination Glove
Legally marketed device to which substantial equivalence is being claimed.	The Nugard Nitril examination glove described in this 510(k) is substantially equivalent to the nitrile examination glove currently being marketed.
Description of device	Nugard Nitril meet the requirement for examination glove described by the American Standard for Testing and Material ASTM D 3578 with the exception of ultimate elongation before aging. It is blue in color and prepowdered. Sizes available is from XS - XL

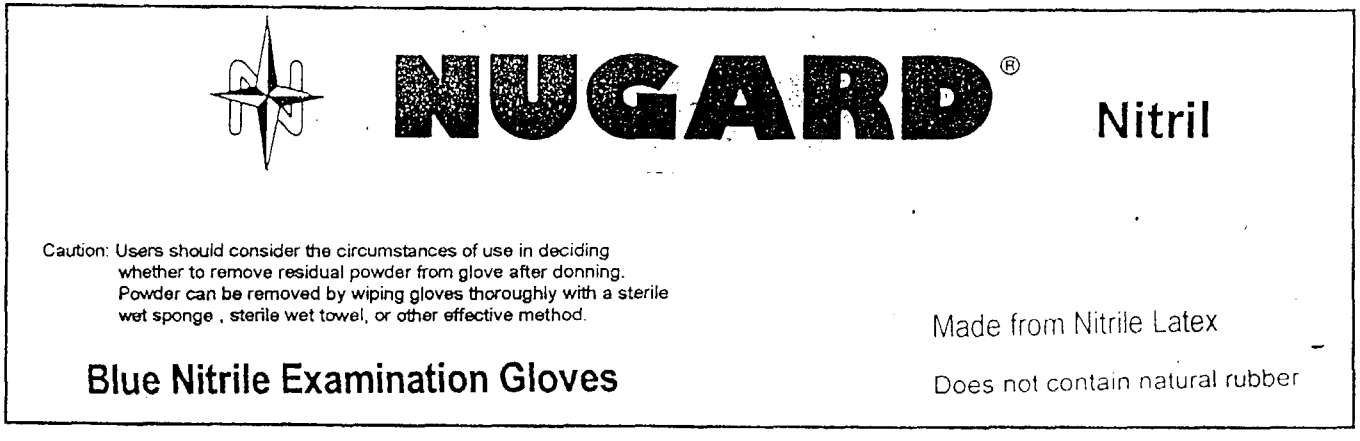
Intended Use of the device	These nitrile examination gloves are to be worn by healthcare workers or similar personnel during work to prevent cross contamination between the user and the patient.
Summary of technological characteristics compared to predicate device	This notification describes the similarities to the approved device described.
Brief description of non-clinical tests	Test conducted per ASTM D3578, ASTM D512 indicates that the product meet the requirements. Biocompatibility tests are carried out.
Brief description of clinical tests	Not carried out
Conclusion drawn from clinical and non clinical tests	Not applicable
Additional information deemed necessary by the FDA	None

Appendix A

Dispenser Box Design



TOP View



Side View

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 1999

Mr. Chin-Guan Low
Managing Director
TERANG NUSA Sdn. Bhd.
1 Jalan 8, Pengkalan Chepa 2 Industrial Zone
16100 Kota Bharu,
Kelantan, MALAYSIA

Re: K990841
Trade Name: Nugard Nitril® Nitrile Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: March 30, 1999
Received: April 6, 1999

Dear Mr. Chin-Guan Low:

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. Indication for use Statement

Applicant	:	Terang Nusa Sdn Bhd
510(k) Number	:	Not available
Device Name	:	Patient Examination Glove K990841
Trade Name	:	NUGARD Nitril ® Prepowdered, USP, BLUE

Indication for use :

The examination gloves are to be worn by healthcare workers or similar personnel during work to prevent cross contamination between the user and the patient.

Concurrence of CDHR Office of Device Evaluation (ODE)

Bruce C. for Chen
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K990841

Prescription Use _____ *OR* Over the counter ✓
Per 21 CFR 801.109