TERANG NUSA Sdn Bhd

510(k) Summary
SENSIFLEX Powderfree Latex Examination Glove

K990488

510(k) Summary

Submitter Name	Terang Nusa Sdn Bhd
Submitter Address	1, 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	23 Apr 99
Trade Name	SENSIFLEX
Common Name	Latex Examination Glove
Classification	Patient Examination Glove
Legally marketed device to which substantial equivalence is being claimed.	The SENSIFLEX powderfree latex examination glove described in this 510(k) is substantially equivalent to the UNISEAL Gloves, powderfree that is currently marketed.
Description of device	SENSIFLEX meet the requirement for examination gloves described by the American Standard for Testing and Material ASTM D3578, white in color and non-powdered. Sizes available is from XS – XL

MAY 28

K990488

TERANG NUSA Sdn Bhd

510(k) Summary
SENSIFLEX Powderfree Latex Examination Glove

Intended Use of the device	These 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 marketed device	There is no variation in technological characteristics.
Brief description of non-clinical tests	Test conducted per ASTM D3578, ASTM D512 indicates that the product meet the requirements. Primary Skin irritation test ASTM F 719-81 Dermal sensitization Test ASTM F 720-81 (86) indicates no sensitization or irritation. Final product is iodine tested for starch free status.
Brief description of clinical tests	Not carried out
Conclusion drawn from clinical and non clinical tests	Non-clinical tests and biocompatibility tests indicate device meet all performance and biocompatibility requirements.
Additional information deemed necessary by the FDA	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 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: K990488
Trade Name: SENSIFLEX Powder-Free Latex Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: April 26, 1999
Received: April 30, 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,

for

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

Submitter	:	Terang Nusa Sdn Bhd
510(k) Number	:	~~Not available~~ K990488
Device Name	:	Powderfree Latex Examination Glove
Trade Name	:	SENSIFLEX

Indication for use :

These examination gloves are for use by healthcare workers or similar personnel during work to prevent cross contamination or cross infection between the user and the patient.

Concurrence of CDHR Office of Device Evaluation (ODE)

Alan S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K 990488

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