

K982957

JAN 13 1999



TERANG NUSA Sdn Bhd

510(k) Summary for SENSIFLEX Powderfree Surgeon's Glove

510(k) Summary

Submitter Name	Terang Nusa Sdn Bhd
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Contact Person	LOW , Chin Guan
Date of preparation	15 Aug 98
Trade Name	SENSIFLEX
Common Name	Surgeon's Glove
Classification	Surgeon's Glove
Legally marketed device to which substantial equivalence is being claimed.	The SENSIFLEX powderfree surgeon's glove described in this 510(k) is substantially equivalent to the powdered SUR-G GLOV currently being marketed. The difference between the two is the additional manufacturing process that removes the powder from the glove.
Description of device	SENSIFLEX meet the requirement for surgeon's glove described by the American Standard for Testing and Material ASTM D3577 as Type 1, white in color and non-powdered. Sizes available is from 6 - 9.

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Intended Use of the device	These surgeon's gloves are to be worn by healthcare workers or similar personnel during procedures or in any work to prevent cross contamination between the user and the patient.
Summary of technological characteristics compared to predicate device	This notification describes the minor changes to the manufacturing process that removes the powder from the device.
Brief description of non-clinical tests	<p>Test conducted per ASTM D3577, ASTM D512 indicates that the product meet the requirements.</p> <p>Primary Skin Irritation in Rabbit Test ASTM F 719-81 and Dermal Sensitization Test ASTM F 720 - 81 (86) indicates no sensitization or irritation.</p> <p>Final product is iodine tested for starch free status.</p>
Brief description of clinical tests	Not carried out
Conclusion drawn from clinical and non clinical tests	Non-clinical and bio-compatibility test indicate device meet all performance and bio-compatibility requirements.
Additional information deemed necessary by the FDA	None



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 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: K982957
Trade Name: Sensiflex Powder-Free Latex Surgeon's Gloves
Regulatory Class: I
Product Code: KGO
Dated: November 9, 1998
Received: November 12, 1998

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 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). 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.

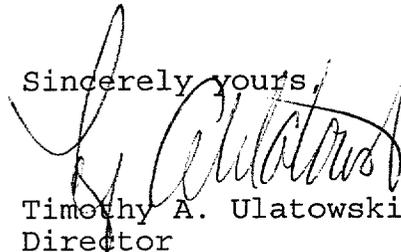
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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 pre-market 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" (21CFR 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/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



TERANG NUSA Sdn Bhd
510(k) Submission for Surgeon's Gloves

510(k) Number : K 982957
Device Name : SENSIFLEX Powderfree Latex Surgeon's Glove

Indication For Use :

A surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination

Concurrence of CDHR Office of Device Evaluation (ODE)

George A. Wells for Chia S. Lim, PhD

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number _____

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