JAN 2 9 1998

K974356

510(k) Summary

Applicant	:	Terang Nusa Sdn Bhd
Address	:	Lot E4(4), Jalan 8 Pengkalan Chepa II FTZ 16100 Kota Bharu Kelantan, Malaysia
Tel Fax	:	+ 60 (9) 773 5133 + 60 (9) 773 7755
Contact Person	:	LOW, Chin Guan (Managing Director) Nikolaus WEISS (QA Manager)
Summary prepared by	:	LOW, Chin Guan
Date	:	15 July 1997

1. Device Name

General Name	:	Surgical Glove Surgeon's Glove
Proprietary Name	:	SUR-G GLOV®
Classification	:	Surgeon's Glove 21 CFR Part 878.4460
Classification Code	:	79 KGO

2. Substantial Equivalence Comparison Product

The device is compared to

i)	Product	:	Triflex Surgeon's Glove
	Manufactured by	:	Travenol Laboratories
	510(k)	:	K832448
	Classification	:	Surgeon's Glove 21 CFR Part 878.4460
	Quality Standard	:	ASTM D-3577

ii)	Product	:	Comfit Surgeon's Glove
	Manufactured by	:	Wembley Rubber Products
	510(k)	:	K903446
	Classification	:	Surgeon's Glove 21 CFR Part 878.4460
	Quality Standard	:	ASTM D-3577

3. Intended Use of Device

The surgeon's gloves are sterile gloves worn by surgeons, healthcare workers or similar personnel during surgical procedures to prevent contamination between the user and the patient.

4. Details of comparison data (substantial equivalence)

Areas of similarity	SUR-G GLOV®	TRIFLEX	COMFIT
Indications for Use	Yes	Yes	Yes
Design	Anatomical	Anatomical	Anatomical
Materials	Natural Latex	Natural Latex	Natural Latex
Performance	Per ASTM D3577	Per ASTM D3577	Per ASTM D3577
Sterility	Yes	Yes	Yes
Biocompatibility	Yes	Yes	Yes
Physical properties	Per ASTM D3577	Per ASTM D3577	Per ASTM D3577
Chemical Safety	Yes	Yes	Yes
Sterilization Method	Gamma Radiation	Gamma Radiation	Gamma Radiation
Compatibility of material with environment	Natural Rubber	Natural Rubber	Natural Rubber
Usage	Hospitals, Clinic, Ambulance Nursing Homes	Hospitals, Clinic, Ambulance Nursing Homes	Hospitals, Clinic, Ambulance Nursing Homes
Standards met	ASTM D3577	ASTM D3577	ASTM D3577
Shelf Life	5 years	5 years	5 years
W.S. Protein < 120 µg/g	Yes	No	No

5. Design

The device is designed to comply with the physical measurements of ASTM D 3577.

Product described as : Surgeon's Gloves or Surgical Gloves.
Anatomical in shape
Hand Specific (Left or Right)

Sizes available :
6
6½
7
7½
8
8½
9

Product Specification : ASTM D 3577 (91)
: EN 455 Part 1 & 2 (94)
EN 552 (94)
EN 556 (94)

6. Material of Manufacture (Raw Materials)

The following are the raw materials and chemical used in the manufacture of the product .

	Chemical Name
Natural Rubber Latex	-
Sulphur	S
Zinc Oxide	ZnO
ZDEC	Zinc Diethyldithiocarbamate
ZDBC	Zinc Dibuthyldithiocarbamate
Titanium Dioxide	TiO_2
Antioxidant	Styrenated Phenol
Absorbable Corn Starch	-

7. Performance

Characteristics			SUR-G GLOV®	ASTM D 3577 (91)
Width Size	6		76 ± 3	76 ± 6
	6½		83 ± 3	83 ± 6
	7		90 ± 3	89 ± 6
	7½		95 ± 3	95 ± 6
	8		103 ± 3	102 ± 6
	8½		109 ± 3	108 ± 6
	9		115 ± 3	114 ± 6
Length (min)			280	265
Thickness	Palm	mm	0.21 ± 0.02	0.10
	Finger	mm	0.23 ± 0.02	0.10
	Cuff	mm	0.21 ± 0.02	0.10
Tensile Strength	Min	(Unaged)	27 Mpa	24 Mpa
		(Aged)	24 Mpa	18 Mpa
Elongation @ break		(Unaged)	830%	750% min
		(Aged)	800%	560% min
Modulus @ 500 % elongation		(max.)	4.0 Mpa	5.5 Mpa
External powder level			80 ± 25 mg	NA
Internal powder level			90 ± 25 mg	NA

A test certificate of the above is in *Appendix B.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 1998

Mr. Tony K. Djie
President
American Health Products, Incorporated
528 Amapola Avenue
Torrance, California 90501-1215

Re: K974356
Trade Name: Surgeon's Gloves, Powdered, Latex, Sterile
"Surg-G-Glov®"
Regulatory Class: I
Product Code: KGO
Dated: December 31, 1997
Received: December 31, 1997

Dear Mr Djie:

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 current Good Manufacturing Practice requirement, 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 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) 594-4618. 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" (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	:	Surgeon's Gloves
Trade Name	:	SUR-G GLOV ®

Indication for use :

The surgeon's gloves are sterile gloves to be worn by surgeons, healthcare workers or similar personnel during surgical procedures to prevent contamination between the user and the patient.

Concurrence of CDHR Office of Device Evaluation (ODE)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974356

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