

**SRI ANUSHAM RUBBER INDUSTRIES
PRIVATE LIMITED
100% EXPORT ORIENTED UNIT**

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TEL: 91 4652 33091 Pioneer Manikandan Buildings
FAX: 91 4652 32871 Vadasery, Nagercoil-629001.
TLX: 436 209 SIVA IN Tamil Nadu, S India.

MAY 21 1999

K984395

1.0 510K SUMMARY as required by : 807.92(c)

2.0 APPLICANT.

NAME : SRI ANUSHAM RUBBER INDUSTRIES (P) LTD
PIONEER MANIKANDAN BUILDINGS
VADASERRY, NAGERCOIL-629001
TAMIL NADU , S.INDIA

PHONE : + 91 4652 33091

FAX : + 91 4652 32871

CONTACT PERSON : MR. N.PARAMASIVAN
MANAGING DIRECTOR

DEVICE TRADE NAME : NIL

3. COMMON NAME : Surgeon's Glove

4. LEGALLY MARKETED DEVICE TO WHICH
COMPANAY CLAIMING EQUIVALENCE :

Class 1- Surgeon's Gloves (Pre-Powdered) 79KGO
that meets all the requirements of
ASTM D 3577 - 91.

Type 1 - Gloves compounded primarily from Natural Rubber
Latex.

5. DESCRIPTION OF THE DEVICE:

Class 1- Surgeon's Gloves (Pre-Powdered) 79KGO
that meets all the requirements of
ASTM D 3577 - 91.

6 INTENDED USE OF THE DEVICE:

Surgeon's glove is a medical device intended to be worn by
operating room personel to protect a surgical wound from
contamination.

7.0

TECHNOLOGICAL CHARACTERISTICS OF THE
DEVICE COMPARED TO PREDICATE DEVICE.

Measured Parameters of Latex Surgeon's Gloves Manufactured by SRI ANUSHAM RUBBER INDUSTRIES PRIVATE LIMITED			ASTM D 3578 Requirement for Latex Surgeon's Glove
Characteristics	Size	Value	Prescribed
1. Length	5.5	270-272mm	245 mm minimum
	6	270-272mm	265 mm minimum
	6.5	270-272mm	265 mm minimum
	7	270-272mm	265 mm minimum
	7.5	270-272mm	265 mm minimum
	8	270-272mm	265 mm minimum
	8.5	270-272mm	265 mm minimum
	9	270-272mm	265 mm minimum
	2. Width	5.5	68mm
6		73mm	76 +/- 6 mm
6.5		79mm	83 +/- 6 mm
7		87mm	89 +/- 6 mm
7.5		92mm	95 +/- 6 mm
8		103mm	105 +/- 6 mm
8.5		108mm	108 +/- 6 mm
9		112mm	114 +/- 6 mm

3. Thickness at Cuff, Palm and Finger. tip of all the sizes is 0.12mm, 0.16mm and 0.19mm respectively. As per ASTM D3577-95 the minimum thickness specified at cough, palm and finger is 0.1mm.

PHYSICAL PROPERTIES

CHARACTERISTICS	BEFORE AGEING		AFTER AGEING	
	*SARI VALUE	ASTM D 3577 REQUIREMENT	SARI VALUE	ASTM D 3577 REQUIREMENT
Tensile Strength	31 mpa	24 mpa min.	22mpa	18 mpa min.
Elongation at Break %	950-975%	750% min.	850-900%	560% min.
Modulus at 500% Elongation	3.4 mpa	5.5 mpa (max)	-	-

*SARI - SRI ANUSHAM RUBBER INDUSTRIES PRIVATE LIMITED

PERFORMANCE REQUIREMENT:

Characteristics	Related Defects	Level followed By		AQL followed by SARI	AQL Value as per ASTM D3577
		SARI	As per ASTM D3577		
Sterility	Fails Sterility	As per IP	As per USP	NA	NA
Freedom from Holes	Holes	S4		1.5	1.5
Dimensions	Width Length Thickness	S2	S4	4	4
Physical Property	Tensile Strength Elongation at Break before & after ageing.	S2	S2	4	4

POWDER CONTENT:

SARI VALUE	ASTM REQUIREMENT
120 +/- 20	

PROTEIN CONTENT:

SARI VALUE	FDA REQUIREMENT
80 +/- 20 ppm	Value not fixed

MOISTURE CONTENT:

SARI VALUE	FDA REQUIREMENT
0.8%	Value not fixed

BIO-COMPATABILITY

SARI GLOVE	FDA REQUIREMENT
Biologically Compatible	Biologically Compatible

8.0 PERFORMANCE DATA

The Performance Test Data of the Surgeon's Gloves manufactured by SRI ANUSHAM RUBBER INDUSTRIES PVT. LIMITED is given here-under:

Measured Parameters of Latex Surgeon's Gloves manufactured by SRI ANUSHAM RUBBER INDUSTRIES PRIVATE LIMITED		
Characteristics	Size	Value
1. Length	5.5	270 mm
	6	270 - 272 mm
	6.5	270 - 272 mm
	7	270 - 272 mm
	7.5	270 - 272 mm
	8	270 - 272 mm
	8.5	270 - 272 mm
	9	270 - 272 mm
2. Width	5.5	68mm
	6	73mm
	6.5	79mm
	7	87mm
	7.5	92mm
	8	103mm
	8.5	106mm
	9	112mm

3. Thickness at cough, palm and finger of all the sizes is 0.12, 0.16 and 0.19mm.

PHYSICAL PROPERTIES

CHARACTERISTICS	Before Ageing	After Ageing
Tensile Strength	29 mpa	22 mpa
Elongation at break %	850%	800%

INSPECTION LEVEL OF AQL

CHARACTERISTICS	RELATED DEFECTS	LEVEL	AQL
Sterility	Fails Sterility	As per IP	
Freedom from holes	Holes	S4	1.5
Dimensions	Length, Width & Thickness	S2	4
Physical Properties	Tensile Strength Elongation at Break before & after aging	S2	4

POWDER CONTENT : 120 +/- 20mg per glove

PROTEIN CONTENT : 80 +/- 20 ppm

MOISTURE CONTENT : 0.7% maximum

BIO-COMPATABILITY : Biologically Compatible

9. CLINICAL DATA : Not Applicable

CONCLUSION OF PERFORMANCE OF TEST DATA:

The Surgeon's Gloves manufactured by SRI ANUSHAM RUBBER INDUSTRIES PRIVATE LIMITED;

* Meet or exceed the ASTM D3577-95 Specifications

* Meet FDA Pin Hole Requirements

* Meet Labelling Claim as shown in data under S.No.6

ANY OTHER INFORMATION:

Any other information required by FDA in respect of PRODUCT SAFETY AND EFFECTIVENESS shall be provided on demand.



MAY 21 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SRI Anusham Rubber Industries Pvt. Ltd.
C/O Ms. Latha Kumaraswamy
Authorised/Designated Agent U.S.A.
P.O. Box 5206
Pleasanton, California 94566 U.S.A.

Re: K984395
Trade Name: Surgeon's Gloves
Regulatory Class: I
Product Code: KGO
Dated: March 17, 1999
Received: March 19, 1999

Dear Ms. Kumaraswamy:

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.

Page 2 - Ms. Kumaraswamy

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,



T. Timothy A. Ulatowski

Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Surgeon's glove

Indications For Use:

3.1 INDICATIONS FOR USE

APPLICANT : SRI ANUSHAM RUBBER INDUSTRIES PVT.LTD
 510(K) NO :
 DEVICE NAME : SURGEON'S GLOVES

INDICATIONS FOR USE:

Surgeon's Glove is a medical device intended to be worn by operating room personnel during surgery to protect a surgical wound from contamination.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chin S. Lim

(Division Sign-Off)
 Division of Dental, Infection Control,
 and General Hospital Devices
 510(k) Number 2984395

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X