

NOV 23 1999

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1. 510K SUMMARY as required by: 807.92(c)

1.0 APPLICANT

NAME : **SRIANUSHAM RUBBER INDUSTRIES PVT.LTD.**
ADDRESS : **PIONEER MANIKANDAN BUILDINGS,
VADASERY
NAGAR COIL,
TAMIL NADU,
INDIA - 629001.**
PH.NO. : **91-4652-33091,32506.**
FAX NO : **91-4652-32871**

CONTACT PERSON : **N. PARAMASIVAN**
: **MANAGING DIRECTOR**

3. **DEVICE TRADE NAME** : **NIL**

COMMON NAME : **Surgeon's Glove**

Classification Name : **Powder free Surgeon's Glove**

4. **Legally marketed device to which the company claiming equivalence:**
Class I Surgeon's Glove (Powder free) 79KGO that meets all
the requirements of ASTM D3577.

5. **DESCRIPTION OF THE DEVICE :**

Class I Powder free Surgical Glove 79KGO that meets all 'the requirements of
ASTM D3577.

6.0 **Intended use of the Device:**

Powder free Surgeon's glove is a Powder free Medical Device intended to be worn by
Operating room personnel 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 (Powder free) manufactured by Sri.Anusham Rubber industries Pvt. Ltd			ASTM D3577 Requirement for Latex Surgeon's glove (Powder free)
Characteristics	SIZE	Value	
1. Length	5 ½	270-272 mm	245 mm minimum
	6	270 – 272 mm	265 mm minimum
	6 ½	270 – 272 mm	265 mm minimum
	7	270 – 272 mm	265mm minimum
	7 ½	270 –272 mm	265 mm minimum
	8	270 –272 mm	265 mm minimum
	8 ½	270 – 272 mm	265 mm minimum
	9	270 – 272 mm	265 mm minimum
	2. Width	5 ½	68 mm
6		73mm	76 +/- 6mm
6 ½		79mm	83 +/- 6 mm
7		87mm	99 +/- 6 mm
7 ½		92mm	95 +/- 6 mm
8		103mm	105 +/- 6 mm
8 ½		106mm	108 +/- 6 mm
9		112mm	114 +/- 6 mm

3. Thickness at cuff , Palm and finger tip of all the size is 0 .12, 0 .16 and 0.19mm.

ASTM D3577 requirement for thickness at cuff, palm and finger tip is 0.1 mm minimum.

PHYSICAL PROPERTIES:

Characteristics	BEFORE AGEING		AFTER AGEING	
	SARI Value	ASTM D3577 Requirement	SARI Value	ASTM D3577 Requirement
Tensile Strength	27 mpa	24 mpa	20 mpa	18 mpa min
Elongation at break %	850%	750%	750%	560% min
Modulus at 500 % elongation.	3 mpa	5.5 mpa (max)	-	-

SARI : SRI. ANUSHAM RUBBER INDUSTRIES



PERFORMANCE REQUIREMENT:

Characteristics	Related defects	Level followed By SARI	Level As per ASTM D 3577	AQL followed	AQL as per D3577.
Sterility	Fails sterility	As per IP*	As per USP*	NA	NA
Freedom from Holes	Holes	S4	S4	1.5	1.5
Dimension	Width , Length Thickness.	S2	S2	4	4
Physical Property	Tensile strength , Elongation at break before and after ageing.	S2	S2	4	4

IP – INDIAN PHARMACOPEA**POWDER CONTENT**

SARI VALUE	ASTM REQUIREMENT
Nil Powder	2 mg/glove max

PROTEIN CONTENT:

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

MOISTURE CONTENT:

SARI VALUE	FDA REQUIREMENT
0.8% max	No value fixed

BIOCOMPATABILITY:

SARI GLOVE	FDA REQUIREMENT
Biologically Compatible	Biologically Compatible



8.0. Performance Data:

The performance test data of the powder free surgical gloves manufactured by Sri.Anusham Rubber Industries Pvt.Ltd is given below.

Measured Parameters of Latex Surgeon's gloves (Powder free) manufactured by Anusham Rubber Industries Pvt.Ltd.,		
Characteristics	SIZE	Value
1. Length	5 ½	270 – 272 mm
	6	270 – 272 mm
	6 ½	270 – 272 mm
	7	270 – 272 mm
	7 ½	270 – 272 mm
	8	270 – 272 mm
	8 ½	270 – 272 mm
	9	270 – 272 mm
	2. Width	5 ½
6		73 mm
6 ½		79 mm
7		87 mm
7 ½		92 mm
8		103 mm
8 ½		106 mm
9		112 mm

3. Thickness at cuff , Palm and finger tip of all the size is 0 .12, 0.16 and 0.19 mm.

PHYSICAL PROPERTIES:

Characteristics	Before Ageing	After Ageing
Tensile Strength	27 mpa	20 mpa
Elongation at break %	850%	750%
Modulus at 500 % elongation.	3 mpa	-



PERFORMANCE REQUIREMENT:

Characteristics	Related defects	LEVEL	AQL
Sterility	Fails sterility	As per Indian Pharmacopea	
Freedom from Holes	Holes	S4	1.5
Dimension	Width , Length Thickness.	S2	4
Physical Property	Tensile strength , Elongation at break before and after ageing.	S2	4

POWDER CONTENT : 1 +/- 1 mg per Glove

PROTEIN CONTENT: 80 +/- 20 ppm

MOISTURE CONTENT: 0.8 % max

BIOCOMPATABILITY: Biologically Compatible

9. Clinical Data : NA

10. CONCLUSION OF PERFORMANCE TEST DATA:

The Powder free Surgeon's gloves manufactured by Sri.Anusham Rubber Industries Pvt Ltd

- Meet or exceed the ASTM D3577
- Meet FDA Pin hole Requirement.
- Meet labeling claim as shown by the data in 6

11. ANY OTHER INFORMATION:

Any other information required by FDA regarding product safety and effectiveness will be provided on request.





NOV 23 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. N. Paramasivan
Managing Director
SRI Anusham Rubber Industries
Private, Limited
Pioneer Manikandan Buildings
Vadasery, Nagercoil-629001
Tamil Nadu, S. India

Re: K993349
Trade Name: Surgeon's Glove - Powder Free
Regulatory Class: I
Product Code: KGO
Dated: September 28, 1999
Received: October 5, 1999

Dear Mr. Paramasivan:

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.

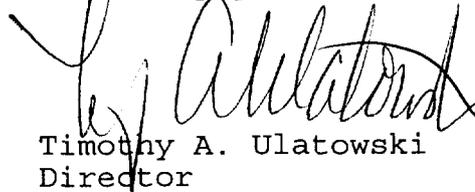
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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

3.0 INDICATIONS FOR USE:

APPLICANT : SRI. ANUSHAM RUBBER INDUSTRIES PVT.I.TD.

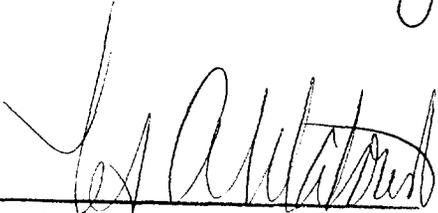
510(K) No. : K99 3349

DEVICE NAME : POWDER FREE SURGEON'S GLOVE

INDICATIONS FOR USE:

Powder free Surgeon's glove is a sterile powder free medical device intended to be worn by operating room personnel to protect a surgical wound from contamination.



OTC  

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993349