

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

TEL: 91 4652 33091 Pioneer Manikandan Buildings,  
FAX: 91 4652 32871 Vadasery, Nagercoil-629001.  
TLX: 486 209 SIVA IN Tamil Nadu, S. India.

Page - 53

JAN 21 1999

K983998

P. 1/5

REVISED

- 1.0 SIOK 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 : Patient Examination Gloves-Powder Free
4. LEGALLY MARKETED DEVICE TO WHICH  
COMPANAY CLAIMING EQUIVALENCE :
  - Class 1- Patient Examination Gloves(Powder Free) B0L YY  
that meets all the requirements of  
ASTM D 3578 - 95.
  - Type 1 - Gloves compounded primarily from Natural Rubber  
Latex.
5. DESCRIPTION OF THE DEVICE:
  - Class 1- Patient Examination Gloves(Powder Free) B0L YY  
that meets all the requirements ASTM D 3578-95.
6. INTENDED USE OF THE DEVICE:
  - Latex Examination Gloves (Powder Free) referred to as medi-  
cal device are worn on hand and fingers by the examiner as  
effective barrier between examiner and patient against  
exposure to micro organism in blood and other body fluids,  
waste and equivilent.

*Stok Submission  
Application Pass - 5/4*

*K983998*

*page 2/5*

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 Examination Glove-Powder free
Characteristics	Size	Value	Prescribed
1. Length	EX-S	240-245mm	220 mm minimum
	S	240-245mm	220 mm minimum
	M	240-245mm	230 mm minimum
	L	245-250mm	230 mm minimum
	EX-L	245-245mm	230 mm minimum
2. Width	EX-S	71mm	70 +/- 6 mm
	S	82mm	80 +/- 6 mm
	M	95mm	95 +/- 6 mm
	L	106mm	111 +/- 6 mm
	EX-L	110mm	114 +/- 6 mm
3. Thickness	EX-R	0.11mm	0.08 mm minimum
	S	0.12mm	0.08 mm minimum
	M	0.12mm	0.08 mm minimum
	L	0.10mm	0.08 mm minimum
	EX-L	0.11mm	0.08 mm minimum

PHYSICAL PROPERTIES

CHARACTERISTICS	BEFORE AGEING		AFTER AGEING	
	*SARI VALUE	ASTM D 3578 REQUIREMENT	SARI VALUE	ASTM D 3578 REQUIREMENT
Tensile Strength	21-24 mpa	14 mpa min.	19-22mpa	14 mpa min
Elongation at Break %	800-850%	700% min.	700-800%	500% min.

\*SARI - SRI ANUSHAM RUBBER INDUSTRIES PRIVATE LIMITED

Stk. Submission  
Application Page - 55

K983998

page 3/5

PERFORMANCE REQUIREMENT:

Characteristics	Related Defects	Level followed By		AQL followed by SARI	AQL Value as per ASTM D3578
		SARI	As per ASTM D3578		
Freedom from Holes Dimensions	Holes	S4	S4	1.5	4
	Width Length Thickness	S2	S2	4	4
Physical Property	Tensile Strength Elongation at Break before & after ageing.	S2	S2	4	4

POWDER CONTENT:

SARI VALUE	ASTM REQUIREMENT
80 +/- 20	2mg/glove max

PROTEIN CONTENT:

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

MOISTURE CONTENT:

SARI VALUE	FDA REQUIREMENT
0.4%	Value not fixed

BIO-COMPATIBILITY

SARI GLOVE	FDA REQUIREMENT
Biologically Compatible	Biologically Compatible

510 k Submission  
Application Page - 56

K983998

Page 4/5

### 8.0 PERFORMANCE DATA

The Performance Test Data of the Powder Free Examination Gloves manufactured by SRI ANUSHAM RUBBER INDUSTRIES PVT. LIMITED is given here-under:

Measured Parameters of Latex Examination Gloves  
(Powder Free) manufactured by SRI ANUSHAM RUBBER  
INDUSTRIES PRIVATE LIMITED

Characteristics	Size	Value
1. Length	Ex-S	240 - 245 mm
	S	240 - 245 mm
	M	240 - 245 mm
	L	245 - 250 mm
	Ex-L	245 - 250 mm
2. Width	Ex-S	71mm
	S	82mm
	M	95mm
	L	106mm
	Ex-L	110mm
3. Thickness	Ex-S	0.11mm
	S	0.12mm
	M	0.12mm
	L	0.10mm
	Ex-L	0.11mm

### PHYSICAL PROPERTIES

CHARACTERISTICS	Before Ageing	After Ageing
Tensile Strength	21-24 mpa	19-22 mpa
Elongation at break %	800-850%	700-800%

510 k Submission  
Application Page - 57

K983998

page 515

INSPECTION LEVEL OF AQL

CHARACTERISTICS	RELATED DEFECTS	LEVEL	AQL
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 : 1 +/- 1 mg per glove  
 PROTEIN CONTENT : 80 +/- 20 ppm  
 MOISTURE CONTENT : 0.4% maximum  
 BIO-COMPATIBILITY : Biologically Compatible  
 9. CLINICAL DATA : Not Applicable

CONCLUSION OF PERFORMANCE OF TEST DATA:

The Powder Free Gloves manufactured by SRI ANUSHAM RUBBER INDUSTRIES PRIVATE LIMITED;

- \* Meet or exceed the ASTM D3578-95 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.



JAN 21 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SRI Anusham Rubber Industries Pvt. Ltd.  
C/O Mrs. Latha Kumaraswamy  
P.O. Box 5206  
Pleasanton, California 94566 USA

Re: K983998  
Trade Name: Powder-Free Latex Examination Gloves  
Regulatory Class: I  
Product Code: Lyy  
Dated: November 4, 1998  
Received: November 9, 1998

Dear Mrs. 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.

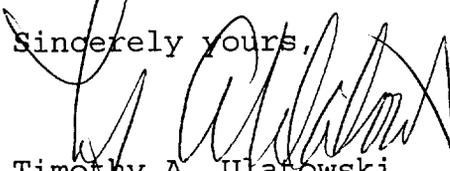
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mrs. 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,



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): K983998

Device Name: Powder Free Latex Examination Gloves

Indications For Use:

3.1 INDICATIONS FOR USE

APPLICANT : SRI ANUSHAM RUBBER INDUSTRIES PVT.LTD  
 510(K) NO :  
 DEVICE NAME : POWDER FREE LATEX EXAMINATION GLOVES

INDICATIONS FOR USE:

Powder Free Latex Examination Glove is a device intended for medical use , worn by the Examiner on his hands / fingers to prevent contamination between Patient and Examiner.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K983998

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X