

NOV 19 1999

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

2.0 APPLICANT

: K993348

NAME

M/s. SRI.ANUSHAM RUBBER INDUSTRIES  
PVT.LTD.

ADDRESS

PIONEER MANIKANDAN BUILDINGS.  
VADASERY,NAGERCOIL,  
TAMIL NADU,  
INDID - 629001.

PH.NO.

: 91-4652- 33091 / 32506 .

FAX NO

: 91-4652- 32871

CONTACT PERSON

: MR. N.PARAMASIVAN  
MANAGING DIRECTOR.

3. DEVICE TRADE NAME

: NIL

COMMON NAME

: Nitrile Examination Glove (Powder free)

4. Legally marketed device to which the company claiming equivalence:

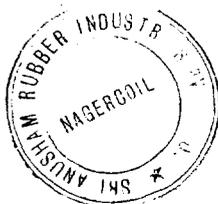
Class I Nitrile Examination Gloves ( Powder free) 80LZA that meets all the requirements of ASTM D3578 - 95.

5. DESCRIPTION OF THE DEVICE :

Class I Nitrile Examination Gloves ( Powder free) 80LZA that meets all the requirements of ASTM D3578- 95.

6. Intended use of the Device:

Nitrile examination glove (Powder free) is a Powder free devices made of Nitrile Latex intended for medical purpose that is worn on the examiners hand or finger to prevent contamination between patient and examiner.



**7.0 TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE  
COMAPARED TO PREDICATE DEVICE.**

Measured Parameters of Nitrile Examination gloves (Powder free) manufactured by Sri.Anusham Rubber industries Pvt. I.td.,			ASTM D3578 Requirement for Nitrile Examination glove (Powder free)
Characteristics	SIZE	Value	
1. Length	EX-S	235-240 mm	220 mm minimum
	S	235-240 mm	220 mm minimum
	M	235-240 mm	230 mm minimum
	L	235-240 mm	230mm minimum
2. Width	EX S	70MM	70 +/- 6 mm
	S	82 mm	80 +/- 6 mm
	M	93 mm	95 +/- 6 mm
	L	107 mm	111+/- 6mm
3. Thickness	EX S	0.10mm	0.08 mm minimum
	S	0.10mm	0.08 mm minimum
	M	0.10mm	0.08 mm minimum
	L	0.10mm	0.08 mm minimum

**PHYSICAL PROPERTIES**

CHARACTERISTICS	BEFORE AGEING		AFTER AGEING	
	SARI VALUE *	ASTD 3578 REQUIREMENT	SARI VALUE	ASTD 3578 Requirement
Tensile Strength	18 - 20 mpa	14 mpa min	16 - 18 mpa	14 mpa min
Elongation at break %	750 - 800%	700% min	650-700%	500% min

SARI - SRI.ANUSHAM RUBBER INDUSTRIES .



**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	Holes	S4	S4	1.5	4
Dimension	Width , Length Thickness.	S2	S2	4	4
Physical Property	Tensile Strength, Elongation at Break.	S2	S2	4	4

**POWDER CONTENT**

SARI VALUE	ASTM REQUIREMENT
Nil Powder	2 mg/glove max

**PROTEIN CONTENT:**

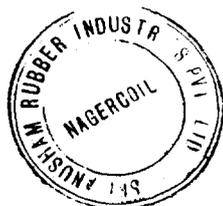
SARI VALUE	FDA REQUIREMENT
30 +/- 10 ppm	Value not fixed.

**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 Nitrile Examination Glove powder free manufactured by SRL ANUSHAM RUBBER INDUSTRIES PVT.LTD. is given below.

Measured Parameters of Nitrile Examination gloves (Powder free) manufactured by Sri.Anusham Rubber Industries Pvt. Ltd.,		
Characteristics	SIZE	Valuc
1. Length	EX-S	235-240 mm
	S	235-240 mm
	M	235-240 mm
	L	235-240 mm
2. Width	EX S	70MM
	S	82 mm
	M	93 mm
	L	107 mm
3. Thickness	EX S	0.10mm
	S	0.10mm
	M	0.10mm
	L	0.10mm

**PHYSICAL PROPERTIES**

CHARACTERISTICS	Before Ageing	After Ageing
Tensile Strength	18 – 20 mpa	16 – 18 mpa
Elongation at break %	750 – 800%	650-700%

**INSPECTION LEVEL OF AQL:**

Characteristics	Related defects	Level	AQL
Freedom from Holes	Holes	S4	1.5
Dimension	Width , Length Thickness.	S2	4
Physical Property	Tensile Strength, Elongation at Break.	S2	4



**POWDER CONTENT : 1 +/- 1 mg per glove**

**PROTEIN CONTENT: 30 +/- 10 ppm**

**MOISTURE CONTENT: .0.8% max**

**BIOCOMPATABILITY: Biologically Compatible.**

**9. Clinical Data : NA**

**7. CONCLUSION OF PERFORMANCE TEST DATA:**

**The Nitrile Examination gloves Powder free manufactured by SRI ANUSHAM RUBBER INDUSTRIES PVT.LTD.**

- Meet or exceed the ASTM D3578
- Meet FDA Pin hole Requirement.
- Meet labelling claim as shown by the data in 6

**8. ANY OTHER INFORMATION:**

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





Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 19 1999

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

Re: K993348  
Trade Name: Nitrile Examination Glove-Powder Free  
Regulatory Class: I  
Product Code: LZA  
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 (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

Page 2 - Mr. Paramasivan

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** : SRLANUSHAM RUBBER INDUSTRIES PVT.LTD.

**510(K) No.** : K 993348

**DEVICE NAME** : NITRILE EXAMINATION GLOVES POWDER FREE

**INDICATIONS FOR USE:**

Nitrile Examination Gloves Powder free is a powder free disposable device made of Nitrile Latex intended for medical purpose, that is worn on the examiners hand or finger to prevent contamination between patient and Examiner.



*S. Lin*

(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K 993348