

SEP 10 1998

K982589

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

**1.0 APPLICANT** :

**NAME** : M/s. SHIVA MEDICARE LIMITED  
**ADDRESS** : A 15, 16, 17(PART)  
MADRAS EXPORT PROCESSINGZONE  
KADAPERI, TAMBARAM,  
CHENNAI 600 045.  
INDIA.

**PH.NO.** : 91-44-2368011/2368322/  
**FAX NO** : 91-44-2368327  
**EMAIL** : shivam@md2.vsnl.net.in

**CONTACT PERSON** : MR. SATISH JAIN  
EXECUTIVE DIRECTOR.

3. **DEVICE TRADE NAME** : NIL  
**COMMON NAME** : Surgeon's Glove

**Classification Name** : Surgeon's Glove

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

5. **DESCRIPTION OF THE DEVICE :**

Class I Surgeon's Glove 79KGO powdered with Absorbable Dusting Powder that meets all the requirements of ASTM D3577.

6.0 **Intended use of the Device:**

Surgeon's glove is a Medical Device intended to be worn by Operating room personnel to protect a surgical wound from contamination.



***Shiva Medicare Limited***

(A 100% Export Oriented Unit)

Registered Office & Works : A 15-17, M.E.P.Z., Kadaperi, Tambaram, Chennai - 600 045 (INDIA)  
Phones : 044/2368011/2368322 EMAIL: shivam@md2.vsnl.net.in Telefax : 091-44-2368327. Grams : "SHIVMEDI"  
Corporate Office : 808, Pragati Tower, 26, Rajendra Place, New Delhi - 110 008 (INDIA)

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7.0 Technological characteristics of the device compared to predicate device.

Measured Parameters of Latex Surgeon's Glove manufactured by Shiva Medicare Ltd.,			ASTMD3577 Requirement for Latex Surgeons glove
Characteristics	SIZE	Value	
1. Length	5 ½	270- 272 mm	245 mm minimum
	6	270 - 272mm	Mm265 mm minimum
	6 ½	270 - 272mm	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 +/- 6 mm
6 ½		79 mm	83 +/- 6mm
7		87mm	99 +/- 6mm
7 ½		92mm	95 +/- 6mm
8		103mm	105 +/- 6mm
8 ½		106mm	108 +/- 6mm
9		112mm	114 +/- 6mm

3. Thickness at cuff , Palm and finger tip of all the size is 0 .12,0 .16 and 0.19 mm. As per ASTM D3577 the minimum thickness specified at cuff palm and finger tip is 0.1 mm.

PHYSICAL PROPERTIES:

Characterstics	BEFORE AGEING		AFTER AGEING	
	SML Value	ASTM D3577	SML Value	ASTD 3577 Requirement
Tensile Strength	27 mpa	24 mpa (min)	20 mpa	18 mpa min
Elongation at break %	850%	750%	750%	560% min
Modulus at 500 % elongation.	3 mpa	5.5 mpa (max)	-	-



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PERFORMANCE REQUIREMENT:

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

POWDER CONTENT

SML VALUE	ASTM REQUIREMENT
120 +/- 20	

PROTEIN CONTENT:

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

MOISTURE CONTENT:

SML VALUE	FDA REQUIREMENT
0.8% max	No value fixed

BIOCOMPATABILITY:

SML GLOVE	FDA REQUIREMENT
Biologically Compatible	Biologically Compatible



**8.0 Performance Data:**

The performance test data of the surgeons gloves manufactured by Shiva Medicare Limited is given below.

Measured Parameters if Latex Surgeon's gloves (Powder free) manufactured by Shiva Medicare Ltd.,		
Characteristics	SIZE	Value
1. Length	5 ½	270 mm
	6	270 - 272mm
	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		73mm
6 ½		79mm
7		87mm
7 ½		92mm
8		103mm
8 ½		106mm
9		112mm

3. Thickness at cuff , Palm and finger tip of all the size is 0.12, 0.16 and 0.19. mm.

**PHYSICAIL PROPERTIES:**

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

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**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 : 120 +/- 20

PROTEIN CONTENT: 80 +/- 20 ppm

MOISTURE CONTENT: 0.8% max

BIOCOMPATABILITY: Biologically Compatible.

9. Clinical Data : NA

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

The Surgeon's gloves manufactured by Shiva Medicare Limited

- Meet or exceed the ASTM D3577
- Meet FDA Pin hole Requirement.
- Meet labelling 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.





Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 10 1998

M/s. Shiva Medicare Ltd.  
C/O Mr. James F. Logan  
Medical Reports Exchange  
314 North Hunter Street  
Baltimore, MD 21202

Re: K982589  
Trade Name: Surgeon's Glove, Latex Powdered Free  
Regulatory Class: I  
Product Code: KGO  
Dated: June 30, 1998  
Received: July 24, 1998

Dear Mr. Logan:

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

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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,

*S. Butman for*

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 : SHIVA MEDICARE LIMITED

510(K) No. : K982589

DEVICE NAME : SURGEON'S GLOVE

INDICATIONS FOR USE:

Surgeon's glove is a medical device intended to be worn by operating room personnel 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)

Prescription Use  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

*George A. Miller for* (Optional Format 1-2-96)

(Division Sign-Off) *Chin S. Tin, PhD*  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K982589