MAY 22 2002

1. 510K SUMMARY as required by: 807.92(c) K014283

1.O APPLICANT :

NAME : **BRIGHTWAY GLOVES PVT.LTD**
ADDRESS PIONEER MANIKANDAN BUILDINGS,
VADASERY
NAGAR COIL,
TAMIL NADU,
INDIA – 629001.
PH.NO. : 91-4652-276291, 276046.
FAX NO : 91-4652-274271

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) 79KGOthat 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 tobe worn by Operating room personnel to protect a surgical wound from contamination.

BRIGHTWAY GLOVES PVT. LTD. NAGERCOIL

7.0 Technological characteristics of the device compared to predicate device.

Measured Parameters of Latex Surgeon's gloves (Powder free) manufactured by Brightway Gloves 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	70 +/- 6 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:

	BEFORE AGEING		AFTER AGEING	
Characteristics	BGPL Value	ASTM D3577 Requirement	BGPL 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)	-	-

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PERFORMANCE REQUIREMENT:

Characteristics	Related defects	Level followed By BGPL	Level As per ASTM D 3577	AQL followed	AQL as per ASTM 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

BGPL VALUE	ASTM REQUIREMENT
Nil Powder	2 mg/glove max

PROTEIN CONTENT:

ARPL VALUE	FDA REQUIREMENT
80 +/- 20 ppm	200 ppm max.

MOISTURE CONTENT:

ARPL VALUE	FDA REQUIREMENT
0.8% max	No value fixed

BIOCOMPATIBILITY:

ARPL GLOVE	FDA REQUIREMENT
Biologically Compatible	Biologically Compatible

8.0. Performance Data:

The performance test data of the powder free surgical gloves manufactured by Brightway Gloves Pvt.Ltd is given below.

Measured Parameters of Latex Surgeon's gloves (Powder free) manufactured by Brightway Gloves 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	68 mm
	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	-

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PERFORMANCE REQUIREMENT:

Characteristics	Related defects	LEVEL	AQL
Sterility	Fails sterility	As per Indian Pharmacopeias	
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 Brightway Gloves 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.

BRIGHTWAY GLOVES PVT. LTD. NAGERCOIL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2002

Mr. N. Paramasivan
Managing Director
Brightway Gloves Private Limited
Pioneer Manikandan Building
Vadasery, Nagar Coil,
Tamil Nadu,
INDIA

Re: K014283
Trade/Device Name: Sterile Latex Surgeons Glove (Powder Free)
Regulation Number: 878.4460
Regulation Name: Surgeons Glove
Regulatory Class: I
Product Code: KGO
Dated: March 23, 2002
Received: April 11, 2002

Dear Mr. N. Paramasivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/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 : BRIGHTWAY GLOVES PVT.LTD.

510(K) No. : K014283

DEVICE NAME : POWDER FREE SURGEON'S GLOVE, STERILE

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.

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(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(K) Number K014283

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