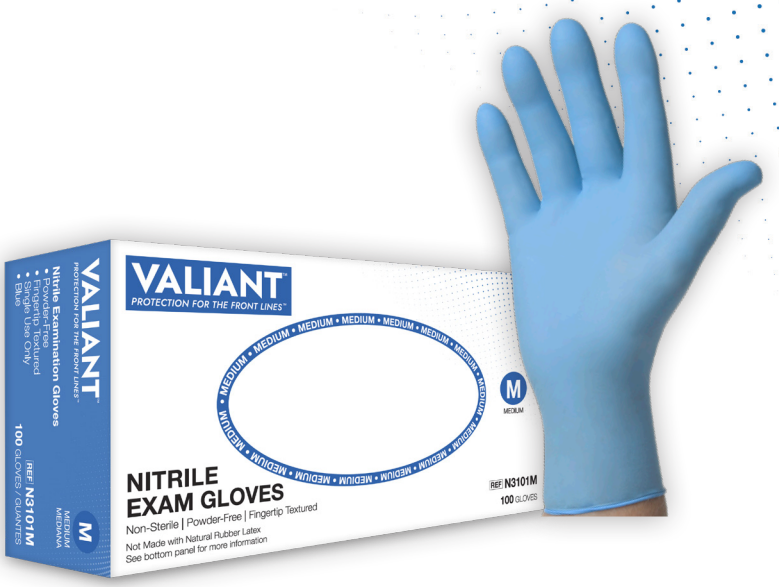
VALIANT™
PROTECTION FOR THE FRONT LINES™

N3101 Series Nitrile Exam Gloves

Features and Benefits

- Nitrile
- Powder Free
- Non-Sterile
- Ambidextrous
- Exam Grade
- Color: Blue
- Texture: Fingertip
- Palm Thickness: 3mil (0.06mm)
- Length: Standard (230mm)
- Cuff: Beaded



Usage

Dependable for house-wide applications within Healthcare, Labs, EMS and other settings where high-use and disposable exam glove protection is important.

Specifications

Usage

Ordering Information

ITEM #	SIZE	GLOVES PER BOX	BOXES PER CASE	GLOVES PER CASE
N3101S	Small	100	10	1000
N3101M	Medium	100	10	1000
N3101L	Large	100	10	1000
N3101XL	X-Large	100	10	1000

VALIANT LLC
Chicago, IL 60618 • www.valiantglobal.com

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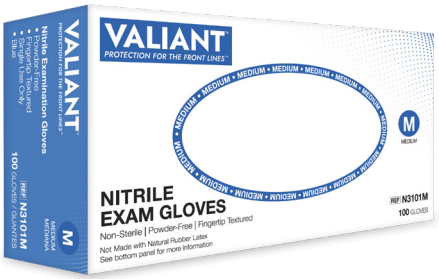
100CT



Spec Information

OVERVIEW	
Material	Nitrile
Powder Content	Powder-Free
Freedom From Holes	1.5 AQL
Surface	Finger Textured
Color	Blue
Cuff Length	230mm, Standard
Not Made With Natural Rubber Latex	Yes

THICKNESS MEASUREMENTS	
Cuff	.06mm / 2.4mil
Palm	.07mm / 2.8mil

PHYSICAL PROPERTIES		
Criteria	Before Aging	After Aging
Tensile Strength	>/= 14	>/= 14
Elongation	500 (min.)	400 (min.)

DIMENSIONS			
Item#	Size	Palm Width (mm)	Length
N3101S	Small	80 ± 10	230mm / standard
N3101M	Medium	95 ± 10	230mm / standard
N3101L	Large	110 ± 10	230mm / standard

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 1998

Mr. Foo Khon Pu
Smart Glove Corporation Sdn. Bhd.
Lot 6487, Bgatu 5 3/4 Sementa, Jalan Kapar,
42100 Klang, Selangor Darul Ehsan,
MALAYSIA

Re: K981349
Trade Name: Smart-Feel Powder Free Nitrile Examination Gloves, (Natural, Blue and Green Colored)
Regulatory Class: I
Product Code: LZA
Dated: April 20, 1998
Received: April 27, 1998

Dear Mr. Foo Khon Pu:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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"(21CFR 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/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

510(k) NUMBER (IF KNOWN): K 981349

DEVICE NAME: SMART-FEEL Powder Free Nitrile Examination Gloves. (Natural, Blue & Green)

INDICATIONS FOR USE:

This glove is disposable and intended for medical purpose that is worn on the examiner's hand 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)

Prescription Use _____ OR Over-The-Counter-Use X
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Lin S. Lim
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981349