

K971945

510(K) SUBMISSION FOR PURE ADVANTAGE POWDER FREE NITRILE HYPOALLERGENIC SURGICAL GLOVE
SUBMISSION DATE: May 29, 1997

SUMMARY OF 510(k) Submission # K971945

JUL 14 1997

A. INFORMATION

1. SUBMITTER'S

NAME:

TILLOTSON HEALTHCARE CORPORATION

ADDRESS:

360 Route 101
Bedford, NH 03110 U.S.A.

TELEPHONE NUMBER:

(603) 472-6600

CONTACT PERSON:

Edward Markovic

DATE SUMMARY PREPARED:

May 29, 1997

2. NAME OF DEVICE

TRADE OR PROPRIETARY NAME:

Pure Advantage Powder Free Nitrile
Hypoallergenic Surgical Glove

COMMON OR USUAL NAME:

Nitrile Powder Free Surgical
Glove Hypoallergenic

CLASSIFICATION NAME:

Surgeon's Glove

3. PREDICATE DEVICE IDENTIFICATION

NAME, NUMBER

1. Pure Advantage Powder Free Nitrile
Surgical Glove K922116

4. DESCRIPTION OF DEVICE

a. HOW THE DEVICE FUNCTIONS:

Nitrile rubber films form an excellent barrier to body fluids and bloodborne pathogens.

b. SCIENTIFIC CONCEPTS THAT FORM THE BASIS FOR THE DEVICE:

The nitrile rubber is water tight under normal conditions of use. It's tensile
properties cause it to conform to the hand, allowing fine movements necessary for
medical treatment. The absence of natural rubber latex in the product yields no
latex protein allergens.

c. PHYSICAL AND PERFORMANCE CHARACTERISTICS SUCH AS DESIGN, MATERIALS AND PHYSICAL PROPERTIES:

Nitrile rubber is known to create a superior barrier to bloodborne pathogens and
body fluids. ASTM conforming tensile properties create a glove that is strong and
flexible. No latex protein allergens and a minimum of curative agents impart
hypoallergenic properties to the glove. The leaching process removes traces of
accelerants that may be chemically irritating. The Powder wash process for powdered
gloves is replaced by a chlorine process. The chlorination process eliminates the
surface drag of the nitrile rubber, thereby eliminating the need for donning powder.

510(K) SUBMISSION FOR PURE ADVANTAGE POWDER FREE NITRILE HYPOALLERGENIC SURGICAL GLOVE
 SUBMISSION DATE: May 29, 1997

SUMMARY OF SAFETY AND EFFECTIVENESS (cont.)

5. STATEMENT OF INTENDED USE, INCLUDING DESCRIPTION OF THE DISEASES OR CONDITIONS THAT THE DEVICE WILL ADDRESS

This is a disposable device, intended for medical purposes, that is worn by operating room personnel to protect a surgical wound from contamination. Hypoallergenic surgical gloves are suitable in situations where health care worker or patient allergic sensitivity may be a factor. Powder free gloves are intended for use in situations where powder is not desirable.

6. EXPLANATION OF SIMILARITIES OR DIFFERENCES TO PREDICATE DEVICE

- The proposed product is identical to the predicate product, except for the following: The proposed product is labeled "Hypoallergenic", and is suitable for situations where a low sensitizing glove is desirable.
- It is powder free, in the same way as predicate product.

B. IF SE DECISION BASED ON PERFORMANCE DATA

1. DISCUSSION OF NON-CLINICAL TESTS

SPECIFICATION	PROPOSED	PREDICATE
	Pure Advantage Powder Free Nitrile Surgical Hypoallergenic	Pure Advantage Powder Free Nitrile Surgical
PERFORMANCE STANDARDS	ASTM	ASTM
WATER TIGHTNESS	ASTM	ASTM

2. DISCUSSION OF CLINICAL TESTS

SPECIFICATION	PROPOSED	PREDICATE
<u>SAFETY</u>		
RABBIT IRRITATION	Passes	Passes
GUINEA PIG MAXIMIZATION	Passes	Passes
MODIFIED DRAIZE REPEAT INSULT PATCH TEST		
- 200 HUMAN SUBJECTS	Passes	Passes

DESCRIPTION OF SUBJECTS

For the Modified Draize Repeat Insult Patch Test, 200 human subjects were used.

The criteria for inclusion in the study was:

Please see Section K-1, for Experimental Design: Inclusion Criteria and Exclusion Criteria



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Edward Markovic
Quality Assurance/Regulatory Manager
Tillotson Healthcare Corporation
360 Route 101
Bedford, New Hampshire 03110

JUL 14 1997

Re: K971945
Trade Name: Pure Advantage Powder Free Nitrile
Hypoallergenic Surgical Sterile Gloves
Regulatory Class: I
Product Code: KGO
Dated: May 27, 1997
Received: May 27, 1997

Dear Mr. Markovic:

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 current Good Manufacturing Practice requirement, 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

Page 2 - Mr. Markovic

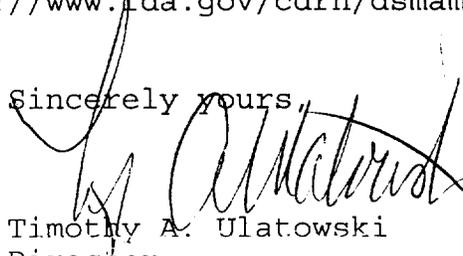
through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Please also be advised that FDA is examining whether the Modified Human Draize Test, as it is currently conducted on medical gloves, is a valid means of predicting the sensitization potential of latex or synthetic materials. If FDA finds that the test is not a scientifically sound means to predict latex or synthetic materials hypersensitivity reactions in users, then hypoallergenic claims included in labeling for medical gloves may be considered misleading, and we will move to have the claim removed from labeling for all medical gloves.

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) 594-4618. 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" (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) SUBMISSION FOR PURE ADVANTAGE POWDER FREE NITRILE HYPOALLERGENIC SURGICAL GLOVE

SUBMISSION DATE: May 29, 1997

510(K) 971945

510(k) Number (if known): 510(k) 971945

Page 1 of 1

Device Name: Pure Advantage Powder Free Nitrile Hypoallergenic Surgical Gloves

Indications For Use:

The *Pure Advantage Powder Free Nitrile Surgical Glove, Hypoallergenic* is "a disposable device intended for medical purposes that is worn by operating room personnel to protect a surgical wound from contamination" (21CFR 878.4460).

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

Representative of CDRI, Office of Device Evaluation (ODE)

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

510(k) Number K971945

Prescription Use _____ OR

Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)