

SEP 12 1997

K 972009

SUMMARY OF 510(k) Submission # K972009

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 Nitrile  
Hypoallergenic Surgical Glove (Unpowdered), Sterile

COMMON OR USUAL NAME: Nitrile Surgical  
Glove Hypoallergenic

CLASSIFICATION NAME: Surgeon's Glove

3. PREDICATE DEVICE IDENTIFICATION NAME, NUMBER

1. Pure Advantage Nitrile  
Surgical Glove K915086

4. DESCRIPTION OF DEVICE

a. 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.

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

The Pure Advantage Nitrile Hypoallergenic Surgical glove is a nitrile rubber product manufactured in accordance with the requirements of ASTM D3577 (TypeII) and ASTM D5151 requirements.

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.

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.

SUMMARY OF SAFETY AND EFFECTIVENESS (cont.)

B. IF SE DECISION BASED ON PERFORMANCE DATA

1. DISCUSSION OF NON-CLINICAL TESTS

SPECIFICATION	PROPOSED	PREDICATE
	<b>Pure Advantage Nitrile Surgical Hypoallergenic</b>	<b>Pure Advantage Nitrile Surgical</b>
PERFORMANCE STANDARDS	<b>ASTM D 3577 [Type 2]</b>	<b>ASTM D 3577 [Type 2]</b>
WATER TIGHTNESS	<b>ASTM D 5151</b>	<b>ASTM D 5151</b>

2. DISCUSSION OF CLINICAL TESTS

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

DESCRIPTION OF SUBJECTS

**For the Modified Draize Repeat Insult Patch Test, 200 human subjects were used. Both the inside surface and outside surface of a medical gloveproduct, Pure Advantage Nitrile Surgical Glove were evaluated to determine its ability to sensitize the skin of a normal volunteer subject using an occlusive repeated insult patch study.**

DISCUSSION OF SAFETY OR EFFECTIVENESS DATA OBTAINED

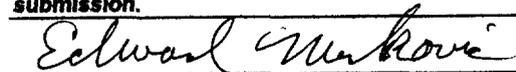
**with specific reference to adverse effects and complications  
Please see Section K-1, for a SUMMARY of the data on testing  
of 200 Human Subjects.**

3. CONCLUSIONS DRAWN FROM NONCLINICAL AND CLINICAL TESTS THAT DEMONSTRATE SAFETY EFFECTIVENESS, AND PERFORMANCE => PREDICATE PRODUCT

**The Pure Advantage Nitrile Hypoallergenic Surgical Glove has been carefully compared to legally marketed devices in the predicate 510(k). The final finished product test data indicate that the proposed product meets acceptable scores in nonclinical tests, and satisfies the requirements for a safe and effective hypoallergenic medical glove.**

**The Pure Advantage Nitrile Hypoallergenic Surgical glove meets the ASTM D3577 (Type I) requirements and ASTM D5151 requirements.**

**Pursuant to 21 C.F.R. 807.87 (j), I, Edward Markovic, Manager QA/Regulatory Affairs certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as the Manager QA/Regulatory Affairs for TILLOTSON HEALTHCARE CORPORATION, and in reliance thereupon, the data and information submitted in this premarket notification are truthful and accurate and that no facts material to a review of the substantial equivalence of this device have been knowingly omitted from this submission.**



Edward Markovic  
Manager QA/Regulatory Affairs



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 12 1997

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

Re: K972009  
Trade Name: Pure Advantage Nitrile Hypoallergenic  
Surgical Glove  
Regulatory Class: I  
Product Code: KGO  
Dated: July 21, 1997  
Received: July 22, 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

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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) Number (if known): 510(k) 972009

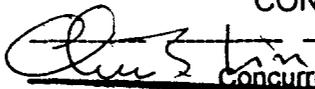
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Device Name: Pure Advantage Nitrile Hypoallergenic  
Surgical Gloves, Sterile, Prepowdered

Indications For Use:

The *Pure Advantage 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  
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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number 972009 OR \_\_\_\_\_

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

Over-The-Counter Use X

(Optional Format 1-2-96)