

4/2/99

SUMMARY OF 510(k) SUBMISSION

K982505

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:

July 20, 1998

2. NAME OF DEVICE  
TRADE OR PROPRIETARY NAME:

Ultra Care Non-Sterile Powder Free  
(GREEN) Natural Rubber Latex  
Patient Examination Glove

COMMON OR USUAL NAME:

Examination Glove

CLASSIFICATION NAME:

Examination Glove

3. PREDICATE DEVICE IDENTIFICATION  
NAME, NUMBER

Ultra Care Non-Sterile Powder Free  
Natural Rubber Latex  
Patient Examination Glove K960247  
1.Substantially Equivalent to Devices  
being marketed in the United States.

4. DESCRIPTION OF DEVICE

a. HOW THE DEVICE FUNCTIONS:

Natural Rubber Latex films form a barrier to body fluids and bloodborne  
pathogens.

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

The Natural rubber is water tight under normal conditions of use. It's tensile  
properties cause it to conform to the hand, allowing movements necessary for  
medical treatment.

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

Natural Rubber Latex is known to create a barrier to bloodborne pathogens and  
and body fluids. ASTM conforming tensile properties create a glove that is strong  
and flexible.  
The glove is manufactured in accordance with the requirements of  
ASTM D3578-95 and ASTM D5151-92.

SUMMARY OF 510(K) SUBMISSION (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 on the examiner's hand to prevent contamination between patient and examiner.**  
**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 equivalent to gloves currently being marketed in the U.S.**

B. IF SE DECISION BASED ON PERFORMANCE DATA

1. DISCUSSION OF NON-CLINICAL TESTS

SPECIFICATION	PROPOSED
PERFORMANCE STANDARDS	<b>ASTM D3578-95</b>
WATER TIGHTNESS	<b>ASTM D5151-92</b>

2. DISCUSSION OF CLINICAL TESTS

SPECIFICATION	PROPOSED
<b><u>SAFETY</u></b>	
RABBIT IRRITATION	<b>Passes</b>
GUINEA PIG SENSITIZATION	<b>Passes</b>

SUMMARY OF 510(K) SUBMISSION (cont.)

**DISCUSSION OF SAFETY OR EFFECTIVENESS DATA OBTAINED**  
***with specific reference to adverse effects and complications***

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

**The Examination Glove has been carefully compared to legally marketed devices in the 510(k). The data summaries indicate that the proposed product meets or exceeds acceptable scores for the predicate product in nonclinical tests, and satisfies the requirements for a safe and effective medical glove.**

**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

APR 2 1999

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

Re: K982505  
Trade Name: Ultra Care Non-sterile Powder-Free (Green)  
Natural Rubber Latex Examination Gloves  
Regulatory Class: I  
Product Code: LYY  
Dated: January 4, 1999  
Received: February 3, 1999

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 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 (Pre-market 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 pre-market notification submission does not affect any obligation you might have under sections 531

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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): K982505

Device Name: *Ultra Care Non-Sterile Powder Free  
(GREEN) Natural Rubber Latex Patient Examination Glove*

**Indications For Use:**

The Examination Glove is "a disposable device intended for medical purposes that is worn on the examiners hand to prevent contamination between patient and examiner".  
(21CFR 880.6250)

(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)

Chin S. Lin  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K982505