

K992428

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SUMMARY OF 510(k) Submission # K

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: Thomas N Tillotson

DATE SUMMARY PREPARED: May, 1997

2. NAME OF DEVICE

TRADE OR PROPRIETARY NAME: Powder Free, Examination Glove  
(with protein content labeling claim)

COMMON OR USUAL NAME: Examination Glove

CLASSIFICATION NAME: Examination Glove

3. PREDICATE DEVICE IDENTIFICATION  
NAME, NUMBER

1. Powder Free,  
Examination Glove K974065  
(with protein content labeling claim)

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 latex 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 leaching process removes traces of chemical accelerants that may be chemically irritating. The glove is manufactured in accordance with the requirements of ASTM D3578-95 and ASTM D5151-92 requirements.

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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 on the examiner's hand to prevent contamination between patient and examiner. Examination gloves with protein content labeling are suitable in situations where healthcare 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 and is suitable for situations where a powder free glove is desirable.**
- **It is powder free, (with protein content labeling claim) in the same way as predicate product.**

B. IF SE DECISION BASED ON PERFORMANCE DATA

1. DISCUSSION OF NON-CLINICAL TESTS

SPECIFICATION	PROPOSED Powder Free  (with protein content)	PREDICATE Powder Free  (with protein content)
PERFORMANCE STANDARDS	ASTM D3578-99	ASTM D3578-99
WATER TIGHTNESS	ASTM D5151-92	ASTM D5151-92
PROTEIN	ASTM D5712-95	ASTM D5712-95

2. DISCUSSION OF CLINICAL TESTS

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

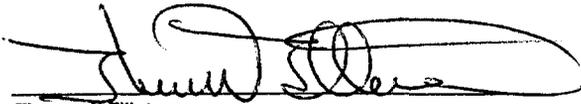
SUMMARY OF SAFETY AND EFFECTIVENESS (cont.)

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

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

**The Powder Free, 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 powder free, (with labeled protein content) medical glove.**

**Pursuant to 21 C.F.R. 807.87 ( j ), I, Thomas N Tillotson, President 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 President 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.**



Thomas N Tillotson  
President



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG -9 1999

Tillotson Healthcare Corporation  
C/O Ms. Carole Stamp  
TUV Product Service  
1775 Old Highway 8 NW, Suite 104  
New Brighton, Minnesota 55112-1891

Re: K992428  
Trade Name: Accutouch Powder Free Natural Rubber Latex  
Patient Examination Glove, Non-sterile  
Regulatory Class: I  
Product Code: LYY  
Dated: July 19, 1999  
Received: July 21, 1999

Dear Ms. Stamp:

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 (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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 through 542 of

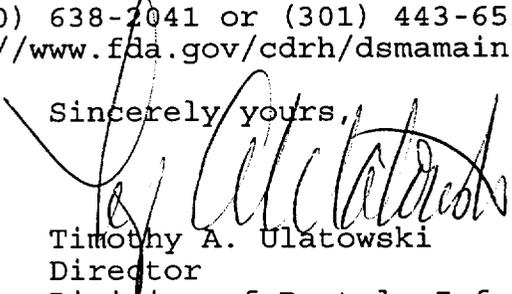
Page 2 - Ms. Stamp

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" (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

3.0 Indications for Use Statement: Include the following or equivalent Indications for Use page. The information, data and labeling claims in the entire 510(k) submission must support and agree with the Indications for Use statement.

**INDICATIONS FOR USE**

Applicant **Tillotson Healthcare**

510(k) Number (if known)

Device Name: **Powder Free Natural Rubber Latex**  
**Patient Examination Glove, Non-sterile**

**Indications For Use:**

The *Powder Free, Examination Glove* is "a disposable device intended for medical purposes that is worn on the examiner's 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 \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The- Counter Use   X  

(Optional Format 1-2-96)

Chiu S. Lin  
(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K 992428