

K974065
JAN. 4, 1998

SUMMARY OF 510(k) Submission # K97

A. INFORMATION

1. SUBMITTER'S
NAME:

TILLOTSON HEALTHCARE CORPORATION

ADDRESS:

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

TELEPHONE NUMBER:

(603) 472-6600

CONTACT PERSON:

Edward Markovic

DATE SUMMARY PREPARED:

October 17, 1997

2. NAME OF DEVICE
TRADE OR PROPRIETARY NAME:

Powder Free, Examination Glove

COMMON OR USUAL NAME:

Examination Glove

CLASSIFICATION NAME:

Examination Glove

3. PREDICATE DEVICE IDENTIFICATION
NAME, NUMBER

1. Powder Free, Hypoallergenic-
Examination Glove K86228
(with low protein claim)

4. DESCRIPTION OF DEVICE

a. HOW THE DEVICE FUNCTIONS:

Natural Rubber Latex films form an excellent 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 fine 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 superior barrier to bloodborne pathogens 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 D3678 and ASTM D5151 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.
Low protein claim surgical gloves 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 low sensitizing glove is desirable.
- It is powder free, (with low protein 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 (low protein)	PREDICATE Powder Free Hypoallergenic (low protein)
PERFORMANCE STANDARDS	ASTM D3578	ASTM D3578
WATER TIGHTNESS	ASTM D5151	ASTM D5151
PROTEIN	ASTM D5712	ASTM D5712

2. DISCUSSION OF CLINICAL TESTS

SPECIFICATION <u>SAFETY</u>	PROPOSED	PREDICATE
RABBIT IRRITATION	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, Hypoallergenic 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, hypoallergenic 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

JAN - 6 1998

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

Re: K974065
Trade Name: Powder Free Latex Examination Glove (with
Protein Claim) 50 micrograms or less of total water
extractable protein per gram
Regulatory Class: I
Product Code: LYY
Dated: October 17, 1997
Received: October 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.

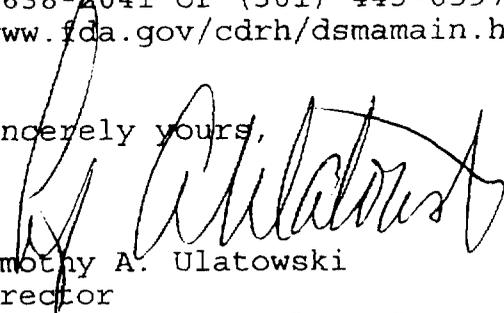
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice 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 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) 594-4618. 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) 974065

Page 1 of 1

Device Name: ^{Latex} Powder Free Examination Glove
(with protein content labeling claim)
This glove contains 80 micrograms or less
of total water extractable protein per gram.

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)

[Signature]
Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number 12974065
Prescription Use OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)