

JUL 29 1996

510(K) SUBMISSION FOR POWDER FREE PLUS HYPOALLERGENIC (WITH LABELED PROTEIN CONTENT) NS EXAM GLOVE  
 ORIGINAL SUBMISSION DATE: JANUARY 18, 1996  
 SUPPLEMENTAL SUBMISSION DATE: MAY 17, 1996  
 REVISION DATE: JULY 26, 1996

K 960225

## 510(K) SUMMARY

## (A) INFORMATION

1. SUBMITTER'S NAME TILLOTSON HEALTHCARE CORPORATION
- ADDRESS 360 Route 101  
Bedford, NH 03110 USA
- TELEPHONE NUMBER (603) 472-6600
- CONTACT PERSON Imogene Tibbetts
- DATE SUMMARY PREPARED July 26, 1996
2. NAME OF DEVICE POWDER FREE PLUS HYPOALLERGENIC  
TRADE OR PROPRIETARY NAME (WITH LABELED PROTEIN CONTENT)  
Non-Sterile Patient Examination Glove
- COMMON OR USUAL NAME Non-Sterile Powder Free Patient Examination Glove
- CLASSIFICATION NAME Patient Examination Glove
3. PREDICATE DEVICE IDENTIFICATION NAME, NUMBER
1. POWDER FREE PLUS PATIENT EXAM GLOVE  
(WITH LABELED PROTEIN CONTENT),  
K954855, SE 12/28/95
2. CUT RESISTANT GLOVE KIT  
WITH HYPOALLERGENIC INNER GLOVE  
#K910383
4. DESCRIPTION OF DEVICE  
Patient examination gloves are made with intact natural latex rubber film, which provides a barrier to body fluids and bloodborne pathogens and between patient and examiner.
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. Gloves with labeled protein content 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 should not be used. Hypoallergenic gloves are appropriate for users who may have a previous sensitivity.

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6. EXPLANATION OF SIMILARITIES OR DIFFERENCES TO PREDICATE DEVICE

1. **SIMILARITIES**

*Proposed and Predicate #1*

- The proposed product is physically identical to the predicate #1 in all respects.
- It is powder free, in the same way as its predicate #1.  
 Both predicate #1 and proposed will be labeled with protein content.
- The processing of the Proposed product is identical to Product #1.

PREDICATE	PROPOSED
<b>POWDER FREE PLUS</b> (WITH LABELED PROTEIN CONTENT) (#K954855 details on file)  5 step washing/leaching process.	<b>POWDER FREE PLUS</b> HYPOALLERGENIC (WITH LABELED PROTEIN CONTENT)  5 step washing/leaching process.

*Proposed & Predicate #2*

- Both Predicate #2 and Proposed product have passed a Modified Draize Repeat Insult Patch Test on human subjects, and have been found hypoallergenic.
- They are both labeled "Hypoallergenic".

2. **DIFFERENCES - LABELING: INTENDED USE**

*Proposed and Predicate #1*

The labeling for both products will be the same, including all required label statements. The difference is the statement, "Hypoallergenic" for the proposed. The proposed product is suitable in situations where health care worker or patient allergic sensitivity may be a factor.

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(B) IF THE SE DECISION IS BASED ON PERFORMANCE DATA

1. DISCUSSION OF NON-CLINICAL TESTS

SPECIFICATION	POWDER FREE PLUS (WITH LABELED PROTEIN CONTENT) PATIENT EXAMINATION GLOVE	POWDER FREE PLUS HYPOALLERGENIC (WITH LABELED PROTEIN CONTENT) PATIENT EXAMINATION GLOVE
	PREDICATE	PROPOSED
PHYSICAL DIMENSIONS	ASTM (Passes)	ASTM (Passes)
PHYSICAL PROPERTIES	ASTM (Passes)	ASTM (Passes)
WATER TIGHTNESS	ASTM (Passes)	ASTM (Passes)

2. DISCUSSION OF PRE-CLINICAL TESTS

SPECIFICATION	PREDICATE	PROPOSED
<u>SAFETY</u> RABBIT SKIN IRRITATION	Passes ( #s 1 and 2 )	Passes
GUINEA PIG SENSITISATION	Passes ( #s 1 and 2 )	Passes

3. DISCUSSION OF CLINICAL TESTS

SPECIFICATION	PREDICATE	PROPOSED
MODIFIED DRAIZE REPEAT INSULT PATCH TEST ON 200 (300) HUMAN SUBJECTS <u>Predicate #2</u>	Passed ( # 2 ) Predicate Product: Glove Kit, etc. 200 Human Subjects	Passes Proposed Product: Hypoallergenic 300 Human Subjects

DESCRIPTION OF SUBJECTS

For the Modified Draize Repeat Insult Patch Test, 300 human subjects were used.

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

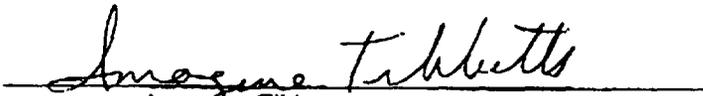
Both the inside surface and the outside surface of POWDER FREE PLUS HYPOALLERGENIC (WITH LABELED PROTEIN CONTENT) LATEX PATIENT EXAMINATION GLOVES were evaluated to determine their ability to sensitize the skin of normal volunteer subjects using occlusive repeated insult patch study. About three hundred persons at three different locations completed the study. Under the conditions employed in this study, there was no evidence of sensitization.

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4. CONCLUSIONS DRAWN FROM NON-CLINICAL, PRE-CLINICAL AND CLINICAL TESTS THAT DEMONSTRATE SAFETY, EFFECTIVENESS, AND PERFORMANCE => PREDICATE PRODUCT

The *POWDER FREE PLUS HYPOALLERGENIC LATEX EXAM GLOVE (WITH LABELED PROTEIN CONTENT)* has been compared to legally marketed devices in the 510(k). The data summaries indicate that the proposed product meets acceptable scores for the predicate products in physical, non-clinical and clinical tests.

Pursuant to 21 C.F.R. 807.87 (j), I Imogene Tibbetts, Director of Medical and Scientific Support Services, 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 Director of Medical and Scientific Support Services 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.



Imogene Tibbetts  
Director of Medical and Scientific Support Services