JUL 29 1996

510(K) SUMMARY

K960247

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:	Imogene Tibbetts
DATE SUMMARY PREPARED:	December 27, 1995

2. NAME OF DEVICE

TRADE OR PROPRIETARY NAME:	Ultra Care Powder Free Hypoallergenic Non-Sterile Examination Glove
COMMON OR USUAL NAME:	Non-Sterile Powder Free Patient Examination Glove Hypoallergenic
CLASSIFICATION NAME:	Patient Examination Glove

3. PREDICATE DEVICE IDENTIFICATION

NAME, NUMBER	1. Formula One Patient Exam Glove K891939 2. Sensi Shield Glove Kit, Inner Glove, K910383 (Hypoallergenic)

4. DESCRIPTION OF DEVICE

Patient examination gloves are made with an 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.
Hypoallergenic patient examination 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 should not be used.

6. EXPLANATION OF SIMILARITIES OR DIFFERENCES TO PREDICATE DEVICE

- **The proposed product is identical to the predicate product #1 in the following respects:**

1. SPECIFICATIONS, ESPECIALLY WATER TIGHTNESS
The specifications for both gloves are identical with respect to water tightness and all physical parameters such as tensile and elongation. Results of testing demonstrate equivalence.

2. FORMULATION OF LATEX

- **The formulation for the latex layer is identical in the proposed and predicate #1 gloves.**

3. IT IS HYPOALLERGENIC

- **Both Predicate #2 and Proposed product have passed a Modified Draize Repeat Insult Patch Test on human subjects, and have been found hypoallergenic.**

- **The proposed product is different from the predicate product #1 in the following respects:**

1. FORMULATION/PROCESSING - METHOD FOR RENDERING GLOVE powder free.
The proposed product has an additional "slip coat" composed of a proprietary polyurethane coating, as a substitute for donning powder.

2. NO DONNING POWDER is added.

3. PROCESSING
The proposed product has two extra leach steps in its process.

4. LABELING: INTENDED USE
The labeling for both products will be substantially the same, including all required label statements. The main differences from predicate #1 are the statements "Powder Free" and "Hypoallergenic".

510(K) SUMMARY (continued)

B. IF SE DECISION BASED ON PERFORMANCE DATA

1. DISCUSSION OF NON-CLINICAL TESTS

SPECIFICATION	PREDICATE	PROPOSED
	1. Formula One Patient Examination Glove 2. Sensi Shield Glove Kit Hypoallergenic Inner Glove	Ultra Care Powder Free Hypoallergenic Patient Examination Glove
PERFORMANCE STANDARDS	ASTM (#1)	ASTM
WATER TIGHTNESS	ASTM (#1 and #2)	ASTM

2. DISCUSSION OF CLINICAL TESTS

SPECIFICATION	PREDICATE	PROPOSED
SAFETY		
RABBIT SKIN IRRITATION	Passes (#1 and #2)	Passes
GUINEA PIG SENSITIZATION	Passes (#1 and #2)	Passes
MODIFIED DRAIZE REPEAT INSULT PATCH TEST	Passes (# 2) on 200 human subjects	Passes on 300 human subjects

DESCRIPTION OF SUBJECTS

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 Ultra Care Powder Free Hypoallergenic 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

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

The Ultra Care Powder Free Hypoallergenic Exam Glove 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, nonclinical 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

Imogene Tibbetts
Director of Medical and Scientific Support Services