FEB 7 2000

510(K) SUMMARY K994131

AMBIDERM POWDER FREE (COLORED) LATEX EXAMINATION GLOVES WITH PROTEIN CLAIMS OF 50 MICROGRAMS OR LESS PER GRAMS

Submitter's Name:	**MEDTEXX PARTNERS INC.**
Submitter's Address:	
Name of Contact Person:	
Date of Preparation:	**December 6, 1999**
Name of Device:	
Trade Name:	**AMBIDERM POWDER FREE LATEX EXAMINATION GLOVES WITH PROTEIN CLAIMS OF 50 MICROGRAMS OR LESS PER GRAM**
Common Name:	**Latex Examination Gloves**
Classification Name:	**Patient Examination Gloves**
Legally Marketed Device to Which Equivalency is Being Claimed:	**Ambiderm Powder Free Latex Examination Gloves as described in the 510(k) notification are substantially equivalent to the class I patient examination glove 80LYY. It meets all the current spec listed under the ASTM specification D 3578-99 standard specification for rubber examination gloves.**
Description of the Device:	**Ambiderm Powder Free Latex Examination Gloves with Protein Labeling Claim meet the current specifications listed under the ASTM specifications D 3578-99 standard specification for rubber examination gloves. They are black in color.**

Intended Use of the Device:	**Ambiderm Powder Free Latex Examination Gloves are intended for single use for medical purposes and are worn on the hand of health care and similar personnel to prevent contamination between the health care personnel and the patient.**
Summary of Technological Characteristics Compared to the Predicate Device:	**There are no different technological characteristics. Gloves are made from natural rubber compound and the initial products are powder free latex examination gloves.**
Brief Discussion of Nonclinical Tests:	**Testing is performed as per ASTM D 3578-99 and 21 CFR 800.20. Gloves meet all the current specifications listed under the ASTM specifications D 3578-99 standard specification for latex examination gloves.** **Primary skin irritation testing in the rabbit and delayed contact sensitization testing in the guinea pig indicate no irritation or sensitization.** **Final product is negative for the test for presence of starch using the USP iodine test.**
Brief Discussion of Clinical Tests:	**No new clinical test were conducted under this 510(K)**
Conclusions Drawn for the Nonclinical and Clinical Tests:	**Nonclinical laboratory and animal data indicate that the pre-powdered natural product meets all performance and biocompatibility requirements.**
Other information Deemed Necessary by FDA:	**Not Applicable**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 7 2000

Medtexx Partners, Incorporated
c/o Mr. E.J. Smith
Smith Associates
P.O. Box 4341
Crofton, Maryland 21114

Re: K994131
Trade Name: AMBIDERM Powder Free Latex Examination Gloves (Black Colored), with Protein Claims of 50 Micrograms or Less Per Gram
Regulatory Class: I
Product Code: LYY
Dated: November 30, 1999
Received: December 7, 1999

Dear Mr. Smith:

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 (Premarket 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 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) 594-4692. 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

510(k) Number (if known):

Device Name: AMBIDERM Powder Free Latex Examination Gloves (Black Colored), with Protein Claims of 50 Micrograms or Less Per Gram.

Classification Panel: 80LYY

Indications for Use:

AMBIDERM Powder Free Latex Examination Glove (Black Colored), polymer coated, with a protein labeling claim is a single use device intended for medical purposes that is worn on the hand of health care and similar personnel to prevent contamination between the health care personnel and the patient.

(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

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994131