MAY - 4 2005

K040916

510(k) Summary

Date: March 24, 2004

Submitter:
VitalCare Group Inc.
8935 NW 27th Street
Miami Fl. 33172

Contact:
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Establishment Number: 1063200

Address of Manufacturing Site:
VitalCare Malaysia, SDN BHD, Inc.
Lot 7, Jalan 16/11
Shah Alan – Selangor
Malaysia

Name of Device: VitalCare Powder Free Synthetic Vinyl Examination Glove

Predicate Device: VitalCare Vinyl Powdered Examination Glove

Device Common and Classification Name(s):

Common Name: Powder Free Exam Glove
Classification Name: Glove, Patient Examination, Vinyl

Classification Information:

Class:	Class I
Panel:	General Hospital
Product Code:	LYZ
Cite:	880.6250

Intended Use of the New Device: A patient examination glove is a disposable device intended for medical purposes that is worn on the hand of healthcare professional and similar personnel to prevent contamination between the healthcare personnel and the patient's body, fluids, waste or environment

Guidance Documents: ASTM –D-5250-00, ASTM- D-6124-01, FDA 1000 ml Water Leak Test.

Feature\Claim	Detail	Predicate
Intended Use	A patient examination glove is a disposable device intended for medical purposes that is worn on the hand of healthcare professional and similar personnel to prevent contamination between the healthcare personnel and the patient's body, fluids, waste or environment	Similar
Materials	Vinyl, Synthetic Plastic Bag Corrugated	Similar Similar Similar
Labeling	VitalCare Powder Free Synthetic Vinyl Examination Glove Reorder Number Size Quantity Non – Sterile, pouch and shipping case Manufacturer Address	Powdered Similar Similar Similar Similar Similar Similar
Packaging	One plastic bag, 100 pouches per case	Similar

Labels, Labeling: See Attachments

Package labels: Copies of the labels for the Powder Free Synthetic Vinyl Exam glove pouch and shipping case are included. See Attachment 1

Promotional Materials: No promotional materials have been developed for this device.

Engineering Drawings: Engineering drawings, with dimensions and tolerances, are included in Attachment 2

Performance Data: VitalCare Powder Free Vinyl Examination Glove meets all requirements for ASTM Standard D-5250-00 physical and dimensional testing, ASTM D6124-01 for starch to determine the gloves meet the powder free claim, no more than 2mg powder per glove. FDA 1000ml Water Leak Test. Primary Skin Irritation and Skin Sensitization tests demonstrate no skin irritation or sensitization.

Comparative Claims: No comparative claims are made for the VitalCare Powder Free Synthetic Vinyl Examination glove. The glove is not claimed as hypoallergenic. It will not be compared in labeling or advertising to other devices.

Unique Designs: The design of the VitalCare Powder Free Vinyl Examination Glove is not unique.

Sterilization Information: Bulk Non - Sterile

Description of the Marketed Equivalent Device: Classified by FDA's General Hospital Panel as Class I, 21 CFR 880.6250, Powdered Vinyl Examination Glove, 880 LYZ meets all the requirements of ASTM Standard D5250-00

Device Trade or Proprietary Name: VitalCare Powdered Vinyl Examination Glove

Device Common and Classification Name(s):

Common Name: Powdered Exam Glove
Classification Name: Glove, Patient Examination, Vinyl

Classification Information:

Class I

Panel: General Hospital

Product Code: LYZ

Cite: 880.6250

Document Control Number: K 992289

Type of Device: Patient Examination Glove

Use with other devices: N\A

Intended Use of the Marketed Equivalent Device: A patient examination glove is a disposable device intended for medical purposes that is worn on the hand of healthcare professional and similar personnel to prevent contamination between the healthcare personnel and the patient's body, fluids, waste or environment.

Labels and Labeling: See Attachment 3

Summary of technological characteristics of new device compared to predicate device: The proposed device has the same technological characteristics and is substantially equivalent to the predicate device, however, the glove is not powdered.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2005

Mr. Michael McAvenia
Director, Quality Assurance
VitalCare Group, Incorporated
15800 NW 13th Avenue
Miami, Florida 33169

Re: K040916
Trade/Device Name: VitalCare Powder Free Synthetic\Vinyl Examination Glove
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: February 1, 2005
Received: April 20, 2005

Dear Mr. McAvenia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040916

Device Name: VitalCare Powder Free Synthetic\Vinyl Examination Glove

Indications for Use: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between the patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K 040 916