



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

OON Corporation Resources  
C/O Ms. Janna P. Tucker  
Tucker & Associates  
198 Ave De La D'Emerald  
Sparks, Nevada 89434-9550

MAR 23 2011

Re: K103650

Trade/Device Name: Non-Sterile, Powder-Free, Blue Latex Examination Gloves  
with Protein Content Labeling Claim (50 Micrograms or less)  
Non-Sterile, Powder-Free Latex Examination Gloves with  
Bubble Gum Scent and Protein Labeling Claim (50 micrograms  
or less)  
Non-Sterile, Powder-Free Blue Latex Examination Gloves with  
Grape Scent and Protein Labeling Claim (50 Micrograms or less)

Regulation Number: 21 CFR 880.6250  
Regulation Name: Patient Examination Glove  
Regulatory Class: I  
Product Code: LYY  
Dated: February 24, 2011  
Received: March 1, 2011

Dear Ms. Tucker:

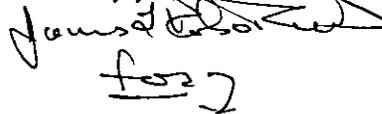
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.  
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

APPLICANT: OON CORPORATION RESOURCES (M) SDN BHD

510(k) NUMBER    K103650

### DEVICE NAME:

Non-Sterile, Powder-Free Blue Latex Examination Gloves with Protein Content Labeling Claim (50 Micrograms or less)

Non-Sterile, Powder-Free Blue Latex Examination Gloves with Bubble Gum Scent and Protein Labeling Claim (50 Micrograms or less)

Non-Sterile, Powder-Free Blue Latex Examination Gloves with Grape Scent and Protein Labeling Claim (50 Micrograms or less)

### Indication For Use:

**A Powder-Free Patient Examination Glove is a Disposable Device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.**

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801.Subpart D)

and/or

Over-The-Counter   
21 CFR 801.Subpart C

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Elizabeth F. Clamie-Walker*  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:    K103650

*Clamie*

*Revised 2-11-2011  
Janna P. Tucker*