

DEC 16 1997

510(k) Summary *K973699*
ULTRALON* POWDER FREE LATEX SURGICAL GLOVES
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| Submitter's Name: | Johnson & Johnson Medical Inc. |
| Submitter's Address: | 2500 Arbrook Blvd. Arlington, Texas 76014 |
| Submitter's Phone Number: | (817) 784-4897 |
| Submitter's Fax Number: | (817) 784-5369 |
| Name of Contact Person: | Margaret Marsh |
| Date of Preparation: | September 26, 1997 |
| Name of Device: Trade Name: Common Name: Classification Name: | ULTRALON* Powder Free Latex Surgical Gloves Surgical Gloves Surgeon's Gloves |
| Legally Marketed Device to Which Equivalency is Being Claimed: | ULTRALON* Powder Free Latex Surgical Gloves as described in this 510(k) notification are substantially equivalent to the currently marketed NEUTRALON* Brown Latex Surgical Gloves. Both are latex gloves with an inner non-latex polymer lining. |
| Description of the Device: | ULTRALON* Powder Free Latex Surgical Gloves meet the description of Rubber Surgical Gloves as described in American Society for Testing Materials (ASTM D 3577-91) as Type 1 gloves compounded primarily from natural rubber latex. They are unpigmented and are powder free. They are packaged sterile in pairs in size 5-1/2 through size 9. |

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| Intended Use of the Device: | ULTRALON* Powder Free Latex Surgical Gloves are intended to protect the wearer from liquids such as body fluids and blood, as well as to protect surgical wounds or sterile fields from microbiological contamination from the wearer. |
| Summary of Technological Characteristics Compared to the Predicate Device: | The predicate and the current glove are similar in technology in that they are both latex gloves with an inner non-latex polymer lining. They are dissimilar in pigmentation (the predicate is a brown glove), and in the presence of powder (the predicate is a powdered glove). |
| Brief Discussion of Nonclinical Tests: | <p>Testing performed per ASTM D-3577-91 and 21 CFR 800.20 indicates that the product meets the requirements of these standards.</p> <p>Primary skin irritation testing in the rabbit and delayed contact sensitization testing in the guinea pig indicate no irritation or sensitization.</p> <p>Final product is negative for the presence of starch using the USP iodine test.</p> |
| Brief Discussion of Clinical Tests: | No new clinical tests were conducted under this 510(k). |
| Conclusions Drawn for the Nonclinical and Clinical Tests: | See Nonclinical Test Section above. |
| Other Information Deemed Necessary by FDA: | Not applicable |

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 1997

Ms. Margaret L. Marsh
Senior Project Manager, Regulatory Affairs
Johnson & Johnson Medical, Incorporated
2500 Arbrook Boulevard
Arlington, Texas 76004-3130

Re: K973699
Trade Name: ULTRALON™ Powder Free Latex Surgical Glove
Regulatory Class: I
Product Code: KGO
Dated: September 26, 1997
Received: September 29, 1997

Dear Ms. Marsh:

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.

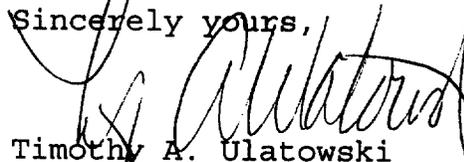
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

Page 2 - Ms. Marsh

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

3.0 Indications for Use Statement

Applicant: Johnson & Johnson Medical, Inc.

510(k) Number (if known): K973699

Device Name: **ULTRALON* Powder Free Latex Surgical Gloves**

Indications For Use:

ULTRALON* Powder Free Latex Surgical Gloves are intended to protect the wearer from liquids such as body fluids and blood, as well as to protect surgical wounds or sterile fields from microbiological contamination from the wearer.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chun S. Lee
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K973699

Prescription Use: _____
(Per 21 CFR 801.109)

OR Over-the-Counter Use: ✓