JUL 29 1999

Maxxim Medical, Inc.
477 Commerce Blvd.
Oldsmar, FL 34677
Phone: 800-727-7951
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Amended 7-13-99 K991615

SUMMARY AND CERTIFICATION
MAXXIM MEDICAL POLYURETHANE POWDER FREE MEDICAL/DENTAL EXAMINATION GLOVES

Class I (classification by the General Hospital and Personal Use Device Panel)

Common Name: Medical Examination Gloves
Dental Examination Gloves

Classification Name: Patient Examination Glove (21 CFR 880.6250)

The purpose of this 510(k) is to obtain an FDA clearance for manufacturing and distributing Polyurethane Powder Free Examination Gloves. The Maxxim Medical Powder Free Polyurethane Medical/Dental Examination glove is substantially equivalent to the Nitra-Touch™ Nitrile Powder Free Medical Examination gloves and SensiCare™ Powder Free Vinyl Medical Examination gloves, originally cleared under K965095 and K944182 respectively. The results of the safety, efficacy and performance testing of the Polyurethane Powder Free Examination Gloves are submitted in this 510(k) submission and are summarized as follows:

1. The gloves meet all ASTM D 3578-95 requirements for freedom from holes, physical properties and physical dimensions, except ultimate elongation before aging.

2. The gloves have been tested and have been shown to be non-irritating and non-sensitizing when tested in accordance with ISO10993-Part 10.

3. The gloves meet requirements of ASTM D 6124-97 for labeling as powder free. No powders are utilized in the manufacture of this glove.

4. The glove is manufactured from a polymer and does not contain any natural rubber latex.

This product is a powder free, non-sterile, polyurethane examination glove that is available in various sizes. It is made with a polyurethane polymer and a polyurethane coating on the user side. This coating provides good donning and doffing without the use of donning powder. No release powder or chemical release agents are used. The gloves will be marketed both as medical examination gloves and dental examination gloves. All requirements for physical properties and dimensions have been met for such uses, based upon comparisons to the predicate devices.

Joyce T. Moody
Signature of Certifier

Joyce T. Moody
(Typed Name)

7-13-99
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 1999

Ms. Joyce T. Moody
Vice President
Regulatory Affairs/Quality Assurance
Maxxim Medical, Incorporated
477 Commerce Boulevard
Oldsmar, Florida 34677

Re: K991615
Trade Name: Polyurethane Powder Free Medical/Dental Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: May 7, 1999
Received: May 10, 1999

Dear Ms. Moody:

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

INDICATIONS FOR USE STATEMENT

Applicant: Maxxim Medical, Inc.

510(k) Number: K991615

Device Name: Maxxim Medical Polyurethane Powder Free Medical/Dental Examination Gloves

Indications for Use:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use _____ Over the Counter X Yes _____
Per 21 CFR 801.109

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991615