MAXXIM MEDICAL

K021452

510(K) Submission: Sterile SensiCare® Advantix™ Powder Free
Polyurethane Medical/ Dental Examination Glove

AUG 01 2002

Attachment 4

Summary of Safety and Effectiveness

Sterile SensiCare® Advantix™ Powder Free
Polyurethane Medical/Dental Examination Glove

Classification:	Class 1
Panel:	Classification by the General Hospital and Personal Use Device
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, importing and distributing a sterile, powder-free, polyurethane examination glove. The Sterile SensiCare® Advantix™ Powder Free Polyurethane Medical/Dental Examination Glove is substantially equivalent to the SensiCare™ Advantix™ Medical/Dental Examination Glove, originally cleared under K 011198.

The results of the safety, efficacy and performance testing of the Sterile SensiCare® Advantix™ Powder Free Polyurethane Medical/Dental Examination Glove are submitted in this 510(k) application and are summarized as follows:

1. The gloves meet all ASTM D 3578-01a requirements for freedom from holes, physical properties and physical dimensions, except ultimate elongation before aging. They meet the same requirements as the gloves cleared under K011198.
2. The gloves have been tested and have been shown to be non-irritating and non-sensitizing when tested in accordance with ISO 10993-Part 10.
3. The gloves meet requirements of ASTM-6124-01 for labeling as powder free. No powders are utilized in the manufacturer of this glove.
4. The glove is manufactured using the same polymer materials as described in K011198.

The product is a powder-free, sterile, polyurethane examination glove that is available in various sizes. It is made with a polyurethane polymer and 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.

There are no adverse changes to the safety and efficacy of the glove products in this submission. The only difference in the proposed glove will be the addition of the sterilization process and the change in packaging (single, pair vs. 100 count/box). Each product will be manufactured to the specifications and per documented label claims in K011198.

Signature of Certifier

4/30/02
Date

Julio Gonzalez
Typed Name

4750 118th Avenue North • Clearwater, FL 33762

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 01 2002

Mr. Julio Gonzalez
Director Quality Assurance
Maxxim Medical
4750 118th Avenue North
Clearwater, Florida 33762

Re: K021452
Trade/Device Name: Sterile SensiCare® Advantix™ Powder Free Polyurethane Medical/Dental Examination Glove
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: June 30, 2002
Received: July 3, 2002

Dear Mr. Gonzalez:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618 . 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
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:	Maxxim Medical, Inc.
510(k) Number (if known):	K021452
Device Name:	Sterile SensiCare® Advantix™ Powder Free Polyurethane Medical/Dental Examination Glove
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 (Per 21 CFR 801.109) OR Over-the-Counter Use_____

(Optional Format 1-2-96)

vision Sign-Off)
vision of Dental, Infection Control,
d General Hospital Devices
10(k) Number K021452