

K994124

AUG 11 2000

MAPA
PROFESSIONAL

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[1] 510 (k) Summary

Date Prepared: November 24, 1999

[2] Applicant.

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Contact Person:

Alejandro Sánchez
Carretera Saltillo-Zacatecas
Entronque a General Cepeda
Km. 17.5 Col. La Encantada
Saltillo, Coahuila
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e-mail: asanchez@interclan.net

[3] Name of Device:

Trade Name:	NIPROTECT
Common Name:	Powder-Free Nitrile Ambidextrous Gloves.
Classification Name:	Patient Examination Glove

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[4] Description:

Classified by FDA's general and Plastic device Panel as Class I (21 CFR 880.6250), NIPROTECT Powder-free Nitrile Ambidextrous Gloves (80LZA). Meets all requirements of ASTM D6319 Standard for Nitrile Examination gloves for medical application.

[5] NIPROTECT Powder-free Nitrile ambidextrous gloves meets the physical requirements of ASTM Standard D6319 Standard for Nitrile Examination gloves for medical application.

[6] Intended Use.

NIPROTECT Powder-free Nitrile Ambidextrous gloves is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

[7] NIPROTECT Powder-free Nitrile Ambidextrous gloves are summarized with the following technological characteristics compare to ASTM or equivalent standards.

Characteristics	Standard
Dimensions	Meets ASTM D 6319
Physical Properties	Meets ASTM D 6319
Tensile Strength, minimum	Meets ASTM D 412
Freedom from holes	Meets ASTM D 6319 Meets ASTM D 5151
Powder Free	Meets ASTM D 6319 Meets ASTM D 6124
Puncture	Meets EN 388

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[8] Comparison to Predicate Device and Equivalence.

Non-clinical Performance Data:

Applicant device conforms fully to ASTM D6319, Standards specifications for Nitrile examination gloves for medical application. It also meets all requirements of ASTM D412-Tensile, ASTM D624-Tear, EN 388-Puncture and ASTM D6124-residual powder. This device is substantially equivalent to those in commercial distribution.

[9] Conclusions:

It is concluded that NIPROTECT Powder-Free Ambidextrous Gloves are safe, effective and substantially equivalent to those currently in commercial distribution. It conforms fully to ASTM D6319, Standard specification for nitrile examination gloves for medical application and 21 CFR170-199 food additives.

[10] This summary will include any other information reasonable deemed necessary by the FDA.



AUG 11 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mapa Professional
C/O Mr. Alejandro Sanchez
Quality Manager
Carretera Saltillo-General
Cepeda 947 Col. La Encantada
Saltillo Coah
MEXICO

Re: K994124
Trade Name: Niprotect Powder-Free Nitrile
Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: July 6, 2000
Received: July 6, 2000

Dear Mr. Sanchez:

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 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). 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.

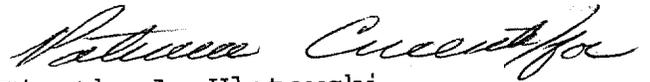
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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 - Mr. Sanchez

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" (21CFR 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/dsma/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



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4.0 Indications for Use Statement.

INDICATIONS FOR USE

Applicant: MAPA PROFESSIONAL
510 (k) Number (if know):* K994124
Device Name: NIPROTECT – Powder free Nitrile 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 or finger 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)

Chiu S. Lin
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994124

Prescription Use _____ OR Over the Counter Use X