K022055

VII. 510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

A. Submitted for

Wilshire Technologies, Inc.
5861 Edison Place
Carlsbad, California 92008
Telephone: (760) 929-7200
Contact: Derek Warneke, Vice President of Operations and Technology
Date Prepared: June __, 2002

B. Device Name

Trade or Proprietary Name:	*DuraCLEAN® with LYCRA®* Medical Examination Glove
Common or Usual Name:	Patient Examination Glove
Classification Name:	Patient Examination Glove

C. Predicate Devices

The subject device is substantially equivalent, in whole or in part, to predicate gloves manufactured by Maxxim Medical (K991615, K010297 and K011198), Wilshire Technologies (K950033), WRP Asia Pacific (K011482 and K012048), SGMP (K020317), and Tactyl Technologies (K955464).

D. Device Description

The subject device is an ambidextrous, powder-free patient examination glove composed of 100% DuPont *LYCRA®* polymer. It is offered non-sterile, in a range of sizes from Extra Small to Extra Large.

The device meets the requirements of applicable recognized standards, including those specified by ASTM D3578, ASTM D6124, ASTM D5151, and the agency's June, 1999 draft *Medical Glove Guidance Manual*.

The device has been demonstrated biocompatible through dermal irritation, dermal sensitization, and cytotoxicity testing in accordance with EN ISO 10993.

E. Intended Use

DuraCLEAN® with LYCRA® Medical Examination Glove is a disposable device made of synthetic LYCRA® polymer that is intended for medical purposes to be worn on the examiner's hand to provide a barrier against potentially infectious materials and other contaminants.

F. Comparison to Predicate Devices

The subject device has the same, or equivalent, indications for use as do other powder-free patient examination gloves cleared for commercial distribution in the U.S.;

The subject device is offered non-sterile, and in a variety of sizes ranging from Extra Small to Extra Extra Large, as are other powder-free patient examination gloves cleared for commercial distribution in the U.S.;

The subject device has the same or equivalent composition as other powder-free examination gloves cleared for commercial distribution in the U.S.;

The subject device conforms to ASTM D3578 in terms of dimensions, physical properties before and after aging, and pinholes, as do other powder-free examination gloves cleared for commercial distribution in the U.S.;

The subject device conforms to ASTM D6124 in terms of weight of powder-free residue, as do other powder-free examination gloves cleared for commercial distribution in the U.S.; and

The subject device has been shown biocompatible through dermal irritation, dermal sensitization and cytotoxicity testing, as have other powder-free examination gloves cleared for commercial distribution in the U.S.

G. Summary of Non-Clinical Tests

In vivo and *in vitro* testing conducted to assess dermal irritation, dermal sensitization, and cytotoxicity, establish that the subject device is biocompatible within the limits of those test.

H. Summary of Clinical Tests

(Not applicable)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 9 2002

Wilshire Technologies
C/O Mr. Steve Reitzler
Regulatory Agent
13221 Maricotte Place
San Diego, California 92130

Re: K022095
Trade/Device Name: DuraCLEAN® with LYCRA® Powder Free Polyurethane Medical Examination Glove
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: June 24, 2002
Received: June 27, 2002

Dear Mr. Reitzler:

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

V. Draft Labeling

A. Indications for Use

510(k) Number (if known): K022095

Device Name: *DuraCLEAN® with LYCRA®* Powder Free Polyurethane Medical Examination Glove

Indications for Use:

DuraCLEAN® with LYCRA® Medical Examination Glove is a disposable device made of synthetic LYCRA® polymer that is intended for medical purposes to be worn on the examiner's hand to provide a barrier against potentially infectious materials and other contaminants.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K022095