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K 981963



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510(k) Summary

Summary of 510(k) Safety and Effectiveness Information

Submitter: Oak Carolina (Darrell Alford)
Division of Oak Technical

Submitters Address: 100 Roe Road
Travelers Rest, SC 29690

Date Prepared: May 29, 1998

Submitters Phone Number: (864) 834-1239

Submitters Fax Number: (864) 834-1219

Trade Name: SensiTex Examination Glove

Common Name: Vinyl Examination Glove

Classification Name: Vinyl Patient Examination Glove

Substantial Equivalence: This device is substantially equivalent to the Maxxim powder free vinyl examination glove.

Device Description: This device is a powder free vinyl examination glove.

Intended Use of the Device: This patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand to prevent contamination between patient and examiner.

510(k) Summary

Technological characteristics and non-clinical performance data comparison of device to predicate device:

* Except for (width) dimensional requirements.

TEST	OAK Vinyl Exam Glove 96-X60 Series	Maxxim Vinyl Exam Glove
Water Leak Test ASTM D5151-92	Pass	Pass
Tensile MPa Ultimate	10.1	13.7
Elongation, Ultimate (%)	326	437
Thickness - Palm (mm)	.178	.130
Thickness - Finger (mm)	.125	.113
Length (mm)	241	241
Width (mm)	S, M, L, XL 95, 105, 118, 124	L 105
Powdered	No	No
ASTM 5250-92	Meets* ASTM 5250-92	Meets ASTM 5250-92

Conclusion drawn from technological characteristics and non-clinical testing:

We conclude that the Oak vinyl exam glove is substantially equivalent to the legally marketed Sencicare powder free medical glove based on the performance data comparison and technological characteristics.



JUL 24 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Darrell W. Alford
Quality Assurance Manager
OAK Carolina, Incorporated
Division of Oak Technical
100 Roe Road
Travelers Rest, South Carolina 29690

Re: K981963
Trade Name: SensiTex Vinyl Examination Glove Powder-Free
Regulatory Class: I
Product Code: LYZ
Dated: May 29, 1998
Received: June 4, 1998

Dear Mr. Alford:

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 (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 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 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" (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,

T. A. Ulatowski for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



CAROLINA INC.

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Statement of Indications For Use

510(k) Number (if known): K981963

Device Name: SensiTex Powder Free Vinyl 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 or fingers 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 X

(Optional Format 1-2-96)

Chin S. Lim

Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number

K981963