FEB 0 4 2002

K013254
510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):

Top Quality Manufacturing
6800 Lindbergh Ave.
Philadelphia, PA 19142

Phone: 1-800-468-4886

Contact Person: Marc Sinkow

Date of Summary: October 25, 2001

Trade Name: Powdered Latex Examination Glove with Aloe Vera

Classification Name: Glove, Patient Examination, Poly

Predicate Device: Top Quality Skingard Polycoat Gloves K004018

Intended Use: The Top Quality Skingard Polycoat Powdered Latex Examination Glove with Aloe Vera is intended for medical purposes to be worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Device Comparison:

	Polycoat Glove with Aloe Vera	Skingard Polycoat Gloves
510(k)		K004018
Testing Completed		
	ASTM D5712-95	Same
	ASTM D3578-00	Same
	ASTM D6124	Same
Intended Use	Examination	Same
Glove	Latex	Same
Packaging	100	100
Glove Coating	Silicone	Silicone
Powdered	Yes	Yes
With Aloe Vera	Yes	No

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 4 2002

Top Quality Manufacturing, Incorporated
C/O Mr. Arthur Ward
Regulatory & Marketing Services, Incorporated
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K013254
Trade/Device Name: Polycoat Powdered Latex Examination Glove with Aloe Vera and Protein Content Labeling Claim (200 Micrograms or Less)
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: October 29, 2001
Received: November 14, 2001

Dear Mr. Ward:

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 Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013254

Device Name: Top Quality Manufacturing, Inc. –Polycoat Powdered Latex Examination Glove with Aloe Vera + PROTEIN CONTENT LABELING CLAIM (200 MICROGRAM OR L

Indications For Use:

The Top Quality Skingard Polycoat Powdered Latex Examination Glove with Aloe Vera is intended for medical purposes to be 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)

Prescription Use_____ OR Over-The-Counter Use ✓

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Clin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013254