MAR 10 2000 K993805



# SUMMARY OF SAFETY AND EFFECTIVENESS

A. INFORMATION

1. SUBMITTER'S

| | |
|---|---|
| Name: | BEST MANUFACTURING COMPANY |
| Address: | 579 Edison Street<br>Menlo, GA 30731 USA |
| Telephone Number: | 706 862 2302 |
| Contact Person: | David C. Young |
| Date Summary Prepared: | 1999-11-08 |

2. NAME OF DEVICE

| | |
|---|---|
| Trade or Proprietary Name: | NITRI-CARE Nitrile Powder-Free Sterile Medical Examination Glove |
| Common or Usual Name | Sterile Nitrile Powder-Free Patient Examination Glove |
| Classification Name: | Patient Examination Glove |

3. PREDICATE DEVICE IDENTIFICATION NAME, NUMBER: N-DEX Nitrile Powder-Free Medical Examination Glove, K992170

4. DESCRIPTION OF DEVICE

a. How the device functions:

Nitrile rubber films form an excellent barrier to body fluids and bloodborne pathogens.

b. Scientific concepts that form the basis for the device:

The nitrile rubber is water tight under normal conditions of use. It's tensile properties cause it to conform to the hand, allowing fine movement necessary for treatment. The absence of natural rubber latex in the product yields no latex protein allergens.

c. Physical and performance characteristics such as design, materials, and physical properties:

Nitrile rubber is known to create a superior barrier to bloodborne pathogens and body fluids.

5. STATEMENT OF INTENDED USE, INCLUDING DESCRIPTION OF THE DISEASE OR CONDITIONS THAT THE DEVICE WILL ADDRESS

This is a disposable device, intended for medical purposes, that is worn on the examiner's hand to prevent contamination between the patient and examiner. Powder-free examination gloves are suitable in situations where powder is not desirable. Sterile gloves are suitable where a sterile examination glove is required.

6. EXPLANATION OF SIMILARITIES OR DIFFERENCES TO PREDICATE DEVICE

- The proposed device is identical to the predicate examination glove K992170 device, except for the following:

  The proposed device is labelled "Sterile".

B. IF SE DECISION BASED ON PERFORMANCE DATA:

1. DISCUSSION OF NON-CLINICAL TESTS

| Specification | Proposed<br>NITRI-CARE Nitrile Powder-Free Sterile Medical Examination Glove | Predicate<br>N-DEX Nitrile Powder-Free Medical Examination Glove |
|---|---|---|
| Performance Standards | ASTM | ASTM |
| Watertightness | ASTM | ASTM |

2. DISCUSSION OF CLINICAL TESTS

| Specification | Proposed | Predicate |
|---|---|---|
| Safety | | |
| Rabbit Irritation | Passes | Passes |
| Guinea Pig Sensitization | Passes | Passes |
| Modified Draze Test (Human Study) | Passes | Passes |

DESCRIPTION OF SUBJECTS

For the Modified Draze Test, 200 human subjects were used. The criteria for inclusion in the study was as discussed in the study, pages 6 and 7, paragraphs 3.11 and 3.12 (see Section N: Human and Animal Testing).

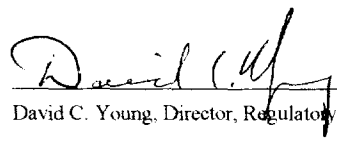
DISCUSSION OF SAFETY OR EFFECTIVENESS DATA OBTAINED
(with specific reference to adverse effects and complications)

See Section N: Human and Animal Testing, page 4 "SUMMARY", of the Modified Draze Test.

3. CONCLUSIONS DRAWN FROM NONCLINICAL AND CLINICAL TESTS THAT DEMONSTRATE SAFETY AND EFFECTIVENESS, AND Performance =/> PREDICATE PRODUCT

The NITRI-CARE Nitrile Powder-Free Sterile Medical Examination Glove has been carefully compared to a legally marketed device in the 510(k). The data summaries indicate that the proposed product meets or exceeds accepted scores for the predicate product in both nonclinical tests and satisfies the requirements for a safe and effective "powder-free" medical glove.

Pursuant to 21 C.F.R. 807.87 (j), I David C. Young, Director, Regulatory Affairs and Quality Assurance, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as the Director, Regulatory Affairs and Quality Assurance, for the Best Manufacturing Company, and in reliance thereupon, the data and information submitted in this premarket notification are truthful and accurate and that no facts material to a review of the substantial equivalence of this device have been knowingly omitted from this submission.



David C. Young, Director, Regulatory Affairs & Quality Assurance

1999-11-08
DATE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2000

Mr. David C. Young
Director, Regulatory Affairs
& Quality Assurance
Best Manufacturing Company
579 Edison Street
Menlo, Georgia 30731-0008

Re: K993805
Trade Name: NITRI-CARE Nitrile Powder-Free Sterile Medical Examination Glove, Blue, Cherry-Flavored
Regulatory Class: I
Product Code: LZA
Dated: February 15, 2000
Received: February 22, 2000

Dear Mr. Young:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

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) 594-4690. 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" (21 CFR 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/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

K993805



## INDICATIONS FOR USE

Applicant: **Best Manufacturing Company**
510(k) Number (if known) *
Device Name: **NITRI-CARE Nitrile Powder-Free Sterile Medical Examination Glove**, Blue, Chemy-flavored

The **NITRI-CARE Nitrile Powder-Free Sterile Medical Examination Glove** is a disposable device intended for medical purposes; that is worn on the examiner's hand, to prevent contamination between the patient and examiner (21 CFR 880.6250).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter X
Per 21 CFR 801.109

* For a new submission, do NOT fill in the 510(k) number blank.



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993805