MAR 1 1 2009

K681970

Registration Number k081970

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

BioClean Chemo Shield

1.	Submitter's name	**Nitritex (M) Sdn. Bhd.**
2.	Submitter's address	**Lot 2935B, Kampung Batau 9 Kebun Baru, Jalan Masjid, 42500 Teluk Panglima Garang, Selangor Darul Ehsan, Malaysia**
3.	Telephone	**603-3122 2614**
4.	Fax	**603-3122 6331**
5.	Date of preparation	17 November 2008
6.	Name of device: Trade Name Common name Classification name	 BioClean Chemo Shield Patient examination glove Glove, Patient Examination, Specialty – 80LZC
7.	Legally marketed device to which equivalency is claimed	The BioClean Chemo Shield is substantially Equivalent to the current Class 1 Patient Examination Glove bearing the product code 80LZC, 21 CFR 880.6250. It meets the current specifications ASTM D 6977-04 and has been tested for chemotherapy agent permeation performance according to ASTM D 6978-05
8.	Description of device	The BioClean Chemo Shield is a powder free, sterile, Polychloroprene examination glove, tested for use with chemotherapy agents.
9.	Intended use of the device	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. Tested for use with Chemotherapy Drugs

<table>
<tr><td>10. Summary of Technological characteristics of the device</td><td>
<table>
<tr><th>Non-clinical tests</th><th>Standard</th><th>Performance</th></tr>
<tr><td>Dimensions</td><td>ASTM D 6977-04</td><td>Met</td></tr>
<tr><td>Physical properties</td><td>ASTM D 6977-04</td><td>Met</td></tr>
<tr><td>Freedom from pinholes</td><td>ASTM D 6977-04</td><td>Met</td></tr>
<tr><td></td><td>ASTM D 5151-06</td><td>Met</td></tr>
<tr><td>Powderfree</td><td>ASTM D 6124-06</td><td>Met</td></tr>
<tr><td>Biocompatibility</td><td>ISO 10993-10: 2002</td><td>Met</td></tr>
<tr><td>Resistance to permeation</td><td>ASTM D 6978-05</td><td>See Data Below</td></tr>
</table>
<table>
<tr><th>Chemotherapy agent tested and concentration</th><th>Breakthrough detection time (minutes)</th></tr>
<tr><td>Cisplatinum,1.0 mg/mL</td><td>No Breakthrough up to 480</td></tr>
<tr><td>Carmustine, 3.3 mg/mL</td><td>50.3</td></tr>
<tr><td>Cyclophosphamide, 20.0 mg/mL</td><td>No Breakthrough up to 480</td></tr>
<tr><td>DoxorubicinHydrochloride</td><td>No Breakthrough up to 480</td></tr>
<tr><td>5-Fluorouracil, 50.0 mg/mL</td><td>No Breakthrough up to 480</td></tr>
<tr><td>Methotrexate, 25.0 mg/mL</td><td>No Breakthrough up to 480</td></tr>
<tr><td>Etoposide, 20.0 mg/mL</td><td>No Breakthrough up to 480</td></tr>
<tr><td>Paclitaxel (Taxol), 6.0 mg/mL</td><td>No Breakthrough up to 480</td></tr>
<tr><td>Thio-Tepa, 10.0 mg/mL</td><td>107.7</td></tr>
</table>
</td></tr>
<tr><td>11. Brief description of clinical tests</td><td>No new clinical tests were required to support this 510(k) application</td></tr>
<tr><td>12. Conclusions from the non-clinical and clinical tests</td><td>The testing carried out confirms that the BioClean Chemo Shield is as safe, as effective and perform as well as the glove performance standards referenced in 10, above and can, therefore be classified as:
Glove, Patient Examination, Specialty – 80LZC</td></tr>
<tr><td>13. Other information deemed necessary by FDA</td><td>None</td></tr>
</table>

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 2009

Mr. Derek Watts
Nitritex (M) Sdn. Bhd.
Lot 2935B, Kampung Batu 9
Kebun Baru, Jalan Masjid
42500 Teluk Panglima Garang
Selangor Darul Ehsan
MALAYSIA

Re: K081970
Trade/Device Name: BioClean Chemo Shield
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: March 5, 2009
Received: March 9, 2009

Dear Mr. Watts:

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud M.D.

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for use

510(k) Number (if known) **K081970**

Device Name BioClean Chemo Shield

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.

Tested for use with Chemotherapy Drugs

Prescription Use (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ✘ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K081970