SEP 16 2011



## *Exhibit # 1 510(k) Summary*

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K111559

1. Date of Submission: May 20, 2011

2. Sponsor
   Shanghai Neo-Medical Import& Export Co.,Ltd
   Room 1503, No.2368, ZhongShanxi Road, Shanghai, 200030, China
   Establishment Registration Number: 3005327291
   Contact Person: Pei Zhang
   Position: Genèral Manager
   Tel: +86-21-54652962
   Fax: +86-21-64673414
   Email: Peter999@neo-medical.net

3. Submission Correspondent
   Ms. Diana Hong & Mr. Lee Fu
   Mid-Link Consulting Co., Ltd
   P.O. Box 237-023, Shanghai, 200237, China
   Tel: +86-21-22815850
   Fax: 240-238-7587
   Email: info@mid-link.net

4. Proposed Device Identification
   Proposed Device Name: Surgical Masks
   Proposed Model: NM-MA-008, NM-MA-010, NM-MA-011 and NM-MA-018
   Classification: II
   Product Code: FXX
   Regulation Number: 21 CFR 878.4040
   Review Panel: General& Plastic Surgery

   Intended Use Statement:

The Surgical Masks are indicated as a protective nose and mouth covering for healthcare workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of microorganism, body fluid.

5. Predicate Device Identification
   510(k) Number: K061864
   Product Name: Non Sterile Surgical Mask
   Manufacturer: Dukal Corporation

6. Device Description
   The Surgical Masks are indicated as a protective nose and mouth covering for healthcare workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of microorganism, body fluid.

   The proposed devices are available in four models with same mask (3-ply) and different configurations, such as ear loop, tie on, eye shield and foam. Detail configurations of them are presented in Table V-1 Surgical Masks Description.

Table III-1 Surgical Masks Description

| Product Model: | Model Description | | | |
|---|---|---|---|---|
| | Mask | Ear loop | Tie on | Shield |
| NM-MA-010 | X | X | | |
| NM-MA-011 | X | | X | |
| NM-MA-008 | X | | X | X |
| NM-MA-018 | X | X | | X |

All of the proposed devices are non-sterile, and only for single use.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies: with the following standards:

a. ASTM F 2100-07 Standard Specification for Performance of Materials Used in Medical Face Masks.
b. Fluid Resistance per ASTM F 1862-07 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)

c. Bacterial Filtration Efficiency (BFE) Test per EN 14683: 2005 Surgical masks, Requirements and test methods.

d. Particulate Filtration Efficiency (Latex Particle Challenge) Test per ASTM F 2299-03 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres

e. Flammability , per16 CFR 1610, Standard for the Flammability of Clothing Textiles; Corrections

f. Differential Pressure (Delta-P) Test per Mil M36954C Military Specification- Mask, Surgical, Disposable

g. Biocompatibility :Cytotoxicity, Sensitization, Irritation

Including: ISO 10993-5:2009 "Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity.

ISO 10993-10:2002 Standard, "Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity"

ISO 10993-10:2002 Standard and Amendment 1, 2006. "Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity AMENDMENT 1"

8. Substantially Equivalent Conclusion

The proposed devices are determined to be Substantially Equivalent (SE) to the predicate device, Non Sterile Surgical Mask (K061864) in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 16 2011

Shanghai Neo Medical Import & Export Company, Limited
C/O Ms. Diana Hong
General Manager
Mid-Link Consulting Company, Limited
P.O. Box 237-023
Shanghai
China 200237

Re: K111559
Trade/Device Name: Surgical Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: August 9, 2011
Received: August 26, 2011

Dear Ms. Hong:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Exhibit #3 IFU Statement

510(k) Number: K111559
Device Name: Surgical Masks
Models: NM-MA-008, NM-MA-010, NM-MA-011, NM-MA-018

Indications for Use:
The Surgical Masks are indicated as a protective nose and mouth covering for healthcare workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of microorganism, body fluid.

☐PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☒OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



Elizabeth E. Claire W

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

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