K122702

MAR 18 2013

5. 510(k) Summary

5.1 Applicant and Correspondent

Name:	Filligent (HK) Limited
Address:	7th Floor, 69 Jervois Street Sheung Wan Hong Kong
Contact Person:	Kai Deusch, M.D., Ph.D. Chief Executive Officer
Phone:	(852) 2542 2400
Date of Preparation:	August 28, 2012

5.2 Manufacturer

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan
Hong Kong

5.3 Name of Device

Trade/Proprietary/Model Name:	BioFriend™ BioMask™ N95 Surgical Respirator Model: Professional BF-200-3013AN
Common Name:	N95 Respirator, Filtering Facepiece Respirator
Classification Name:	N95 Respirator With Antimicrobial/Antiviral Agent Filtering Facepiece Respirator for Use by Healthcare Workers
Classification Regulation:	878.4040
Panel:	General Hospital
Device Class:	Class II
Product Code:	ONT
Recognized Performance Std:	ASTM F2100-11, NIOSH 42 CFR 84 (refer to submission)

5.4 Devices to Which New Device is Substantially Equivalent

Device Name:	BioFriend™ BioMask™ "Premium" BF-200-3013A (Convex)
Manufacturer:	Filligent (HK) Limited
Reference:	K101128
Device Name:	BioFriend™ BioMask™ "Universal" BF-200-2001A (Flat)
Manufacturer:	Filligent (HK) Limited
Reference:	K101128
Device Name:	1870 3M N95 Health Care Particulate Respirator and Surgical Mask
Manufacturer:	3M Company
Reference:	K063023

5.5 Device Description

The BioFriend™ BioMask™ N95 surgical respirator, Model: Professional (BF-200-3013AN) is flat-folded and expands into a convex-shaped mask with polyamide/spandex elastic head-loops to secure the mask to the user's face, and a malleable aluminum strip positioned above the nose for a tighter seal around the nose and face. The respirator is comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. All of the construction materials used in this device are typical construction materials commonly used in surgical facemasks and N95 surgical respirators and being used in current legally marketed devices. The outer active layer of the respirator is coated with a hydrophilic plastic. The second inner layer is treated with copper and zinc ions. Both layers inactivate influenza viruses using different mechanisms of action.

5.6 Statement of Intended Use

The BioFriend™ BioMask™ N95 surgical respirator is a single use NIOSH-approved, disposable N95 surgical respirator with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2% w/w, a pH-lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% w/w and zinc 1.6% w/w which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ N95 surgical respirator inactivates 99.99% of tested influenza viruses on five minutes contact with the surface of the respirator in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: Influenza A subtypes and strains H1N1 (the 2009 pandemic flu subtype A/California/04/2009,

A/Brisbane/59/2007, A/Wisconsin/10/1998, A/New Jersey/8/1976, A/PuertoRico/8/1934), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005), H2N2 (A/2/Japan/305/1957); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/1931); the equine flu subtype: H3N8 (A/Equine/2/Miami/1963); and Influenza B strains: (B/Florida/4/2006, B/Lee/1940), under tested contact conditions. Correlation between in vitro testing results and any clinical event has not been tested.

The BioFriend™ BioMask™ N95 surgical respirator, Model: Professional (BF-200-3013AN) is flat-folded and expands into a convex-shaped mask with polyamide/spandex elastic head-loops to secure the mask to the user's face, and a malleable aluminum strip positioned above the nose for a tighter seal around the nose and face. The device is intended to be worn during seasonal Influenza A or Influenza B, and an Influenza A or Influenza B pandemic. It is intended for occupational use, to help reduce wearer exposure to pathogenic biological airborne particulates, and to protect against the transfer of micro-organisms, body fluids, and particulate material.

5.7 Summary of Technological Characteristics

The BioFriend™ BioMask™ N95 surgical respirator is a single use NIOSH-approved, disposable N95 surgical respirator with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2% w/w, a pH-lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% w/w and zinc 1.6% w/w which form ionic bonds with negatively-charged side-groups on influenza viruses). Both the outer and second inner layers are treated with different compounds that independently inactivate viruses through different mechanisms of action.

The manufacturing methods and construction materials used in the BioFriend™ BioMask™ N95 surgical respirator Professional BF-200-3013AN, are identical to those used in the following FDA-approved predicate devices: the BioFriend™ BioMask™ Universal BF-200-2001A, and the BioFriend™ BioMask™ Premium BF-200-3013A (K101128). Filligent (HK) Limited is the manufacturer of these predicate devices and has complete documentation with respect to the manufacturing methods and materials employed. The above BioFriend™ BioMask™ facemasks are identically comprised of four layers of the same material: an outer layer of spun-bond polypropylene, a second layer of cellulose/polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. The BioFriend™ BioMask™ N95 surgical respirator is also identical in structural shape and design to the following FDA-approved predicate: the BioFriend™ BioMask™ Premium model (BF-200-3013A, convex), except that the meltblown material used in the third layer of the N95 respirator model has

increased filtration specifications (18g/m^2 meltblown polypropylene increased to a 50g/m^2 meltblown polypropylene) to meet the standards required for NIOSH Respirator Certification.

The anti-viral/anti-influenza materials used in the first two active layers of the BioFriend™ BioMask™ N95 surgical respirator are identical in all respects to those of the following FDA-approved predicate devices: the BioFriend™ BioMask™ Universal BF-200-2001A, and the BioFriend™ BioMask™ Premium BF-200-3013A (K101128). Both the outer and second inner layers are treated with different compounds that independently inactivate viruses through different mechanisms of action. Laboratory *(in vitro)* tests conducted demonstrate that, as the active layers are identical in all respects and processed by identical manufacturing methods to those in the above predicates, the BioFriend™ BioMask™ N95 surgical respirator inactivates 99.99% (≥4-logs) of 15 different strains of Influenza A and Influenza B viruses, including the circulating 2009 pandemic H1N1, recent vaccine isolates, major reassortments and avian, swine and equine isolates after 5 minutes contact with the mask surface.

The construction materials used to provide the mechanical filtration in the BioFriend™ BioMask™ N95 surgical respirator – the polypropylene and meltblown materials - are also identical or similar to all of the following predicate devices: the NIOSH-certified Type N95 3M 1870 N95 Health Care Particulate Respirator and Surgical Mask (K063023), and the BioFriend™ BioMask™ surgical facemasks - Universal BF-200-2001A and Premium BF-200-3013A (K101128). The device as a whole is substantially equivalent to all of the predicate devices.

The device as a whole is comprised of identical materials and is processed by identical manufacturing methods to the predicates: the BioFriend™ BioMask™ surgical facemasks Universal BF-200-2001A and Premium BF-200-3013A (K101128), and have been previously approved as biocompatible by irritation and sensitization testing, and toxicological assessment of the products ingredients potentially released with inhalation or salivary contact, and indicates that the facemask and respirator products are safe for use in the intended application. Filligent (HK) Limited is the manufacturer of the predicate devices: the BioFriend™ BioMask™ surgical facemasks - Universal BF-200-2001A and Premium BF-200-3013A (K101128), and has complete documentation with respect to the manufacturing methods and materials employed. Therefore the BioFriend™ BioMask™ N95 surgical respirator raises no new safety issues. The device as a whole is substantially equivalent to these predicate devices.

5.8 Brief description of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

- Bacterial Filtration Efficiency – ASTM F2101
- Sub-micron Particulate Filtration Efficiency – ASTM F2299
- Fluid Penetration Resistance – ASTM F1862
- Breathing Resistance – MIL-M-3654C
- Flammability Testing – 16 CFR 1610
- Biocompatibility - Irritation – ISO 10993-10
- Biocompatibility - Sensitization – ISO 10993-10
- Biocompatibility – Chemical Characterization – ISO 10993-18
- Breathing Resistance – NIOSH 42 CFR 84.180
- Particulate Filtration Efficiency – NIOSH 42 CFR 84.181

5.9 Brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

Not applicable.

5.10 Conclusions drawn from the nonclinical and clinical tests

The performance testing demonstrates that the BioFriend™ BioMask™ N95 surgical respirator is substantially equivalent to the FDA-approved predicate devices, and that it conforms to the recognized FDA consensus standard ASTM F2100-11 Standard Specification for Performance of Materials used in Medical Face Masks and the NIOSH Respirator Certification – 42 CFR 84 – Approval of Respiratory Protective Devices.

The BioFriend™ BioMask™ N95 surgical respirator has been tested for, and appropriately conforms to the requirements set out in ASTM F2100-11 Standard Specification for Performance of Materials Used in Medical Face Masks and NIOSH Respirator Certification 42 CFR 84 - Approval of Respiratory Protective Devices. Performance testing on the BioFriend™ BioMask™ N95 surgical respirator Professional Model BF-200-3013AN has assessed bacterial filtration efficiency, differential pressure, sub-micron particulate filtration efficiency, resistance to penetration by synthetic blood, and flammability. These tests are defined in the FDA Guidance for Industry and FDA Staff, Surgical Masks - Premarket Notification 510(k) Submissions and in the

FDA-recognized consensus standard, ASTM F2100-11 Standard Specification for Performance of Materials used in Medical Face Masks and the NIOSH Respirator Certification – 42 CFR 84 – Approval of Respiratory Protective Devices. Tests were conducted at Nelson Laboratories Inc., Salt Lake City, UT. Virucidal Efficacy testing was carried out at Microbiotest Inc., Sterling, VA. All testing was carried out in compliance with the Good Laboratory Practice (GLP) regulations.

The construction materials used to provide the mechanical filtration in the BioFriend™ BioMask™ N95 surgical respirator – the polypropylene and meltblown materials - are also identical or similar to all of the following predicate devices: the NIOSH-certified Type N95 3M 1870 N95 Health Care Particulate Respirator and Surgical Mask (K063023), and the BioFriend™ BioMask™ surgical facemasks - Universal BF-200-2001A and Premium BF-200-3013A (K101128). The BioFriend™ BioMask™ N95 surgical respirator Professional Model BF-200-3013AN is substantially equivalent as a whole to the predicate devices and is comprised of identical materials and processed by identical manufacturing methods to the following FDA-approved predicate devices: the BioFriend™ BioMask™ Universal BF-200-2001A, and the BioFriend™ BioMask™ Premium BF-200-3013A. Filligent (HK) Limited is the manufacturer of these predicate devices and has complete documentation with respect to the manufacturing methods and materials employed. Therefore the BioFriend™ BioMask™ N95 surgical respirator raises no new safety issues. The BioFriend™ BioMask™ N95 surgical respirator Professional Model BF-200-3013AN is substantially equivalent as a whole to the above predicate devices.

Table 5.1: Performance to ASTM F2100 Level 3 Barrier Medical Facemask - Comparison of the BioFriend™ BioMask™ N95 Surgical Respirator Model: Professional BF-200-3013AN to the Predicate Device, the BioFriend™ BioMask™ Surgical Facemask Model: Premium BF-200-3013A (K101128) and the 1870 3M N95 Health Care Particulate Respirator and Surgical Mask (K063023)

Description	Test Method	BioFriend™ BioMask™ N95 Surgical Respirator Professional BF-200-3013AN	BioFriend™ BioMask™ Surgical Facemasks Universal BF-200-2001A and Premium BF-200-3013A	1870 3M N95 Health Care Particulate Respirator and Surgical Mask
510(k) Number		K122702	K101128	K063023
Product Code		ONT	OUK	MSH
NIOSH Certificate Number		TC-84A-6252	-	TC-84A-3844
Bacterial Filtration Efficiency	ASTM F2101	> 99.9 %	99.9 %	> 99 %
Sub-micron (0.1 µm) Particulate Filtration Efficiency	ASTM F2299	> 99.9 %	99.7 %	Information Not Declared
Differential Pressure (Delta-P)	MIL-M-36954C	4.9 mm H_2O/cm^2	2.6 mm H_2O/cm^2	4.9 mm H_2O/cm^2
Resistance to Penetration by Synthetic Blood	ASTM F1862	160 mm Hg	160 mm Hg	160 mm Hg
Flame Spread	16 CFR Part 1610	Class 1	Class 1	Class 1

Table 5.2: Performance to NIOSH 42 CFR Part 84 - N95 Respirator - Comparison of the BioFriend™ BioMask™ N95 Surgical Respirator Model: Professional BF-200-3013AN to the Predicate Device, the BioFriend™ BioMask™ Surgical Facemask Model: Premium BF-200-3013A (K101128) and the 1870 3M N95 Health Care Particulate Respirator and Surgical Mask (K063023)

Description	Test Method	BioFriend™ BioMask™ N95 Surgical Respirator Professional BF-200-3013AN	BioFriend™ BioMask™ Surgical Facemasks Universal BF-200-2001A and Premium BF-200-3013A	1870 3M N95 Health Care Particulate Respirator and Surgical Mask
510(k) Number		K122702	K101128	K063023
Product Code		ONT	OUK	MSH
NIOSH Certificate Number		TC-84A-6252	-	TC-84A-3844
Particulate Filtration Efficiency (NaCl)	42 CFR 84.181	98 %	N/A	Pass
Breathing Resistance	42 CFR 84.180	8.0 mm H_2O (Inhalation) 8.9 mm H_2O (Exhalation)	N/A	Pass

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 18, 2013

Kai Deusch, M.D., Ph.D.
Chief Executive Officer
Filligent (HK) Limited
7th Floor 69 Jervois Street
Sheung Wan, Hong Kong

Re: K122702
Trade/Device Name: BioFriend™ BioMask™ N95 Surgical Respirator
Model: Professional BF-200-3013AN
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: ONT
Dated: January 14, 2013
Received: February 28, 2013

Dear Dr. Deusch:

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,

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

Enclosure

4 Indications for Use Statement

510(k) Number (if known): K122702

Device Name:

BioFriend™ BioMask™ N95 Surgical Respirator
Model: Professional BF-200-3013AN

Indications for Use:

The BioFriend™ BioMask™ N95 surgical respirator is a single use NIOSH-approved, disposable N95 surgical respirator with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2% w/w, a pH-lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% w/w and zinc 1.6% w/w which form ionic bonds with negatively-charged side-groups on influenza viruses).

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The BioFriend™ BioMask™ N95 surgical respirator, Model: Professional BF-200-3013AN is flat-folded and expands into a convex-shaped mask with polyamide/spandex elastic head-loops to secure the mask to the user's face, and a malleable aluminum strip positioned above the nose for a tighter seal around the nose and face. The device is intended to be worn during seasonal Influenza A or Influenza B, and an Influenza A or Influenza B pandemic. It is intended for occupational use, to help reduce wearer exposure to pathogenic biological airborne particulates, and to protect against the transfer of micro-organisms, body fluids, and particulate material.

Prescription Use _____ AND/OR Over-The Counter Use ___X___
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation

Elizabeth F. Claverie -S
2013.03.18 15:14:51 -04'00'

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

510(k) Number: K122702