January 3, 2019

NBC Meshtec Inc.
% Takahiro Haruyama
President
Globizz Corporation
1411 W. 190th St. Suite 200
Gardena, California 90248

Re: K182766
Trade/Device Name: Cufitec Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: OUK
Dated: December 13, 2018
Received: December 17, 2018

Dear Takahiro Haruyama:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elizabeth F. Claverie -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K182766

Device Name
Cutifec Surgical Mask

Indications for Use *(Describe)*

The Cufitec Surgical Mask is a single-use, disposable surgical mask to cover the nose and mouth of the wearer to protect from the transfer of microorganisms, body fluids and particulates and has an anti-influenza agent (active ingredient: CuI at 0.5% wt. concentration) on the outer and inner mask layers.

The Cufitec Surgical Mask inactivates 99.99% of the following influenza viruses on five minutes contact with the surface of the facemask in laboratory (in vitro) tests against the following influenza viruses:

Influenza A/H1N1: A/WS/33, A/Virginia/ATCC2/2009;
Influenza A/H3N2: A/Kitakyusyu/159/93, A/Udorn/307/72, A/Hong Kong/8/68, A/Victoria/210/09, A/Virginia/ATCC6/2012;
Influenza B: B/Lee/40, B/Taiwan/2/62;
under tested contact conditions.

Correlations between in vitro testing results and any clinical event has not been tested.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1: SUBMITTER INFORMATION

510(k) Owner/Applicant	NBC Meshtec, Inc. 2-50-3 Toyoda, Hino-shi Tokyo, JAPAN, 191-0053 Tel: +81-42-582-1374
NBC Meshtec Correspondent	Tomokazu Nagao, Ph.D. Biology Dept. Manager, R&D NBC Meshtec, Inc.
Official US Correspondent	Takahiro Haruyama Globizz Corporation 1411 W. 190th St., #200 Gardena, CA 90248 Tel: (310) 538-3860 Email: register@globizz.net
Date Prepared	December 21, 2018

2: DEVICE INFORMATION

Trade Name	Cufitec® Surgical Mask
510(k) Number	K182766
Common Name	Surgical Mask with Antimicrobial/Antiviral Agent
Classification Name	Surgical Apparel
Regulation	21 CFR 878.4040
Review Panel	General Hospital
Product Code	OUK
Device Class	Class II

3: PREDICATE DEVICE

Trade Name	BioFriend™ BioMask™ Surgical Facemask Models: Universal BF 200-2001A, Premium BF-200-3013A
Manufacturer	Filligent (HK) Limited
Reference	K101128

4: DEVICE DESCRIPTION

The Cufitec® Surgical Mask is a single-use, disposable device, provided non-sterile, and is intended to cover the nose and mouth of the wearer to protect from the transfer of microorganisms, body fluids, and particulates and has an added anti-influenza agent which inactivates specific pathogens under specified contact conditions. The mask is comprised of four layers of materials: rayon layers with added anti-influenza coating (outer and inner layers) and polypropylene layers (two middle layers). All of the construction materials used in this device are commonly used in the construction of surgical facemasks used in current legally marketed devices. The inner and outer layers are coated with an anti-influenza agent (CuI, 0.5% wt.), which inactivates influenza viruses under tested contact conditions using the same mechanism of action. Masks are held in place on the wearer with ear loops (polyurethane and nylon) and contains a malleable polyethylene nosepiece strip to conform to the wearer's face.

5: INDICATIONS FOR USE

Table A. Comparison of indications for use statements.

Cufitec® Surgical Mask Subject Device	BioFriend™ BioMask™ Surgical Facemask Predicate Device (K101128)
The Cufitec® Surgical Mask is a single-use, disposable surgical mask to cover the nose and mouth of the wearer to protect from the transfer of microorganisms, body fluids and particulates and has an anti-influenza agent (active ingredient: CuI at 0.5% wt. concentration) on the outer and inner mask layers. The Cufitec® Surgical Mask inactivates 99.99% of the following influenza viruses on five minutes' contact with the surface of the facemask in laboratory (in vitro) tests against the following influenza viruses: • Influenza A/H1N1: A/WS/33, A/Virginia/ATCC2/2009; • Influenza A/H3N2: A/Kitakyusyu/159/93, A/Udorn/307/72, A/Hong Kong/8/68, A/Victoria/210/09, A/Virginia/ATCC6/2012; • Influenza B: B/Lee/40, B/Taiwan/2/62; under tested contact conditions. Correlations between in vitro testing results and any clinical event has not been tested.	The BioFriend™ BioMask™ surgical facemasks are single-use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form ionic bonds with negatively-charged side-groups on influenza viruses). The BioFriend™ BioMask™ surgical facemasks inactivate 99.99% of Influenza viruses on five minutes contact with the surface of the facemask 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/07/09, A Brisbane/59/2007, A/Wisconsin /10/98, A/New Jersey/8/79, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005), H2N2 (A/2/JAPAN/305/57); 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/1976/31); the equine flue subtype; H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions. Correlation between in vitro testing results and any clinical event has not been tested.

6: COMPARISON OF DEVICE CHARACTERISTICS

Table B. Comparison of technological characteristics to the predicate device.

Manufacturer	NBC Meshtec Inc.	Filligent (HK) Limited	Significant Differences
Trade Name	Cufitec® Surgical Mask (Subject Device)	BioFriend™ BioMask™ Surgical FaceMask (Predicate Device)	
510(k) No.	K182766	K101128	Same regulatory pathway.
Product Code	OUK	OUK	Same.
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same.
IFU Statement	(See Section 5 above.)	(See Section 5 above.)	Both the subject and predicate devices are intended to protect from the transfer of microorganisms, body fluids, and particulate materials. Both devices have an antiviral agent which inactivates 99.99% of influenza viruses at 5 minutes' contact with the mask surface under tested contact conditions. The primary differences are the active ingredients used and the strains of viruses tested.
Construct	4-ply pleated mask with antiviral agent (L: 8.8 cm x W: 17.5 cm)	4-ply pleated mask with antiviral agent (L: 10 cm x W: 17.5 cm)	Both the subject and predicate devices follow similar constructs and are composed of materials commonly used in the construction of surgical facemasks in current legally marketed devices. The added antiviral agents in both devices are indicated to inactivate 99.99% of influenza virus strains at 5 minutes' contact with the mask surface under tested conditions. The primary differences are the active ingredients used and the layers which are coated to create the desired effect.
Outer layer material	Rayon fabric with CuI antiviral agent	Spun-bond polypropylene with hydrophilic plastic	
2nd layer material	Polypropylene	Cellulose/polyester with copper and zinc	
3rd layer material	Polypropylene	Melt-blown polypropylene	
Inner layer material	Rayon fabric with CuI antiviral agent	Spun-bound polypropylene	
Nosepiece material	Polyethylene	Metal	
Ear loops material	Polyurethane and nylon	Elastic, not made with natural rubber latex	
Active Antiviral Agent	Outer and inner layers: 0.5% CuI (cuprous iodide)	Outer layer: citric acid 2% 2nd layer: copper 1.6% and zinc 1.6%	
Sterility	Non-sterile	Non-sterile	Same.
Shelf Life	12 months	12 months	Same.

Table 5C. Comparison of performance and biocompatibility testing.

Trade Name	Cufitec® Surgical Mask (Subject Device)	BioFriend™ BioMask™ Surgical FaceMask (Predicate Device)	Significant Differences
Performance Testing			
Fluid Resistance	ASTM F1862	ASTM F1862	Same.
Bacterial Filtration Efficiency	ASTM F2101	ASTM F2101	Same.
Particulate Filtration Efficiency	ASTM F2299	ASTM F2299	Same.
Delta Pressure	MIL-M-36945C	MIL-M-36945C	Same.
Flammability	Class 1, 16 CFR Part 1610	Class 1, 16 CFR Part 1610	Same.
Tested Antiviral Efficacy (≥4 log kill)	B/Lee/40	B/Lee/40	Same.
	A/WS/33, A/Virginia/ATCC2/2009, A/Kitakyusyu/159/93, A/Udorn/307/72, A/Hong Kong/8/68, A/Victoria/210//09, A/Virginia/ATCC6/2012, B/Taiwan/2/62	A/New Jersey/8/76, A/California/07/09, A/PR/8/34, A/Swine/1976/31, A/Brisbane/59/2007, A/Wisconsin/10/98, A/Brisbane/10/2007, A/Wisconsin/67/2005, A/2/JAPAN/305/57, NIBRG-14, A/Turkey/Wisconsin/1996, A/Duck/PA/10218/84, A/Equine/2/Miami/63, B/Florida/4/2006	There are differences in the number and subtypes of influenza strains tested for antiviral efficacy.
Clinical Testing	Not applicable.	Not applicable.	Same – clinical testing is not required to support the subject device.
Biocompatibility Testing			
Sensitization	ISO 10993-10	ISO 10993-10	Same.
Irritation	ISO 10993-10	ISO 10993-10	Same.
Ocular Irritation	ISO 10993-10	Not available.	Subject device was tested for ocular irritation in accordance to ISO 10993-10.
Chemical Characterization	ISO 10993-18	ISO 10993-18	Same.

7: SUMMARY OF NON-CLINICAL TESTING

Performance Bench Testing:
The performance testing includes flammability, fluid resistance, bacterial filtration efficiency (BFE), and particle filtration efficiency (PFE). Results of the performance testing met all acceptance criteria per ASTM and ISO standards.

Antiviral testing:
Chemical characterization was conducted to assess the safety of the device when the device is worn. The test included analysis of solids released into airflow through the mask as well as analysis of extracts by saline and hexane. The results of the study support the biological safety of the device.

Limit of Quantitation (LOQ) was designed to determine the limit of active ingredient (CuI) on the mask using uncoated surgical masks. Results demonstrated that the LOQ was 0.048 μg/cm².

Neutralization Validation was performed to validate the neutralization buffer (SCDLP) medium. The results demonstrated that the neutralizer effectively neutralized the antiviral effect of eluted antiviral agent.

Antiviral efficacy was designed to assess both "fresh" and "aged" test articles which were tested against nine subtypes of influenza viruses. The results demonstrate that all test articles met the acceptable criteria of achieving 99.99% reduction of the viruses at 5 minutes' contact.

Determination of resistant strains was performed to determine the strains, out of nine subtypes of influenza, most resistant to both "fresh" and "aged" masks. The results show that the three most resistant strains to the device are Influenza A (H3N2): A/Kitakyusyu/159/93, A/HongKong/8/68, and A/Udorn/307/72.

Simulated breathing test was designed to assess the antiviral efficacy of the device after simulated breathing using "fresh" and "aged" articles against the three most resistant strains of Influenza as well as A/H1N1 (A/Virginia/ATCC2/2009) and Influenza B (B/Lee/40). The results demonstrate that all test articles met the acceptance criteria of achieving 99.99% reduction of the virus at 5 minutes' contact after simulated breathing test.

Repeated exposure testing was conducted to assess both "fresh" and "aged" articles against repeated exposure to Influenza viruses (5 subtypes). The results demonstrate that all test articles met the acceptance criteria of achieving 99.99% reduction of the virus at 5 minutes' contact after simulated breathing test.

Uniform distribution validation was designed to determine the concentration of active ingredient, cuprous iodide (CuI) on the surgical mask. Results show that the concentration of CuI was sufficiently higher than the minimum effective concentration in both "fresh" and "aged" mask samples.

Minimum effective concentration testing was conducted to determine the minimum effective concentration of CuI on the surgical mask using three different concentrations against the influenza viruses (5 subtypes). The minimum concentration of CuI on the mask is sufficiently higher than the minimum effective concentration required for 99.99% reduction of influenza viruses at 5 minutes contact.

7: CONCLUSION

The Cufitec® Surgical Mask and the predicate device are similar in intended use, technological characteristics, and composition of construction materials. Standardized performance and biocompatibility assessments, as well as differences between the devices, did not raise any new concerns regarding safety and effectiveness. The conclusions drawn from the non-clinical performance tests demonstrate that the Cufitec® Surgical Mask is substantially equivalent to the referenced predicate device and is therefore as safe, as effective, and performs as well as or better than the predicate.