November 29, 2019

Innonix Technologies Limited
Reid Borsel
US Agent For Innonix Technologies
10017 Sorrel Ave
Potomac, Maryland 20854

Re: K192105
Trade/Device Name: Innonix Antiviral Child's Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: OUK, OXZ
Dated: October 30, 2019
Received: October 30, 2019

Dear Reid Borsel:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192105

Device Name
Innonix Anti-Influenza Child's Face Mask

Indications for Use *(Describe)*
The Innonix Anti-Influenza Child's Face Mask (Models BF-200-3015A and BF-200-2005A) is a single use, disposable device that is intended to be worn by children (recommended ages 5-10) to cover the nose and mouth to provide a barrier for the respiratory tract for microorganisms, body fluid and particulate materials. The mask is specifically for child or pediatric patients to provide protection for the respiratory tract. This face mask is recommended for use in a healthcare setting with appropriate adult supervision. The Innonix Anti-Influenza Child's Face Mask has hydrophilic plastic coating (active ingredient: citric acid 2%, a pH lowering agent) that rapidly absorbs aerosol droplets away from the outer surface of the mask and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%) that inactivate influenza viruses.

The Innonix Anti-Influenza Child's Face Mask inactivated 99.99% of tested influenza viruses (≥4 log difference versus identical untreated control mask textiles) within five minutes of 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 (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). The mask also inactivated >99.99% of Measles virus strain ATCC VR-24 and Coronavirus 229E strain ATCC VR-740 within one minute of contact with the surface of the facemask in laboratory in vitro tests. Correlation between in vitro 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.

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510(k) Summary K192105

Date Summary was Prepared:	November 28, 2019
Submitter's Name:	Innonix Technologies Limited (formerly Filligent Limited)
Submitter's Address:	13/F, LiFung Centre, 2 On Ping Street Siu Lek Yuen, Shatin Hong Kong
Submitter's Telephone:	Phone +852 2542 2401 Fax +852 2542 2411
US Contact Name:	Reid von Borstel (US Agent for Innonix Technologies Ltd) rvonborstel@usa.net 301-412-4060
Trade or Proprietary Name:	Innonix Anti-Influenza Child's Face Mask Model: BF-200-3015A and BF-200-2005A
510(k) Number Device Classification Name:	K192105 Pediatric/Child Face Mask with Antimicrobial/Antiviral Agent
Classification Name:	CFR 21 878.4040
Panel:	General Hospital
Product Code:	OUK OXZ
Predicate Device:	**Device Name** / **510(k) Number** **Primary Predicate:** BioFriend™ BioMask™Surgical Facemask OUK Models: Universal BF-200-2001. Premium BF-200-3013 — K101128 **Reference Device:** Prestige Ameritech Pediatric/Child's Face Mask OXZ — K160100

1. Device Description

The Innonix Anti-Influenza Child's Face Masks, (both Model BF-200-3015A and BF-200-2005A) comprise 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-bond polypropylene. All of the construction materials used in this device are typical construction materials commonly used in surgical facemasks and being used in current legally marketed devices, and are not made with natural rubber latex. The outer active layer of the face mask is coated with a hydrophilic plastic containing citric acid. The second inner layer is treated with copper and zinc ions. Both of these layers inactivate influenza viruses using different mechanisms of action (pH lowering and ionic disruption).

Model: BF-200-3015A is flat-folded and expands into a convex-shaped mask with polyamide/spandex elastic ear-loops to secure the mask to the user's face, and has a malleable aluminum strip covered with polyurethane foam positioned above the nose for a tighter seal around the nose and face.

Model: BF-200-2005A is a flat pleated mask with polyamide/spandex elastic ear-loops to secure the mask to the user's face, and has a malleable aluminum strip covered with polyurethane foam positioned above the nose for a tighter seal around the nose and face.

2. Indication for Use

The Innonix Anti-Influenza Child's Face Mask (Models BF-200-3015A and BF-200-2005A) is a single use, disposable device that is intended to be worn by children (recommended ages 5-10) to cover the nose and mouth to provide a barrier for the respiratory tract for microorganisms, body fluid and particulate materials. The mask is specifically for child or pediatric patients to provide protection for the respiratory tract. This face mask is recommended for use in a healthcare setting with appropriate adult supervision. The Innonix Anti-Influenza Child's Face Mask has hydrophilic plastic coating (active ingredient: citric acid 2%, a pH lowering agent) that rapidly absorbs aerosol droplets away from the outer surface of the mask and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%) that inactivate influenza viruses.

The Innonix Anti-Influenza Child's Face Mask inactivated 99.99% of tested influenza viruses (≥4 log difference versus identical untreated control mask textiles) within five minutes of 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 (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). The mask also inactivated >99.99% of Measles virus strain ATCC VR-24 and Coronavirus 229E strain ATCC VR-740 within one minute of contact with the surface of the face mask in laboratory in vitro tests. Correlation between in vitro results and any clinical event has not been tested.

3. Technological Characteristic Comparison

Comparison of the predicate device, BioFriend™ BioMask™ Surgical Facemask Models: Premium BF-200-3013A and Universal BF-200-2001A to Innonix Anti-Influenza Child's Face Mask, Models: BF-200-3015A and BF-200-2005A

	BioFriend™ BioMask™ Surgical Facemask Convex Model: BF-200-3013A and BF-200-2001A	**Innonix Anti-Influenza Child's Face Mask, Model: BF-200-3015A and BF-200-2005A**	**Comparison of Subject Device to Predicate**
FDA Predicate #	K101128	K192105	**N/A**
Product Code	OUK	OUK OXZ	**Same:** Both predicate and subject devices use identical virus-inactivating materials in the first and second active layers, and the inner two textile layers are identical as well. **Different:** The subject device is intended to be worn by children. The predicate device is a medical device to be used by adults.
Date Approved	May 26, 2011	November 29, 2019	**N/A**
Description	The BioFriend™ BioMask™ surgical facemask is offered in two mask styles, Models: Universal BF-200-2001A and Premium BF-200 3013A. The Universal model is a standard flat mask with pleats, while the Premium model is flat-folded and expands into a convex-shaped mask. The Premium model also has ear adjusters and an anti-fog nose flap. Both models comprise 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 latex free and are typical construction materials commonly used in surgical facemasks and being used in current legally marketed devices, and are not made with natural rubber latex. The outer active layer of the facemask is coated with a hydrophilic plastic containing citric acid. The second inner layer is treated with copper and zinc ions. Both layers inactivate influenza viruses using different mechanisms of action.	The Innonix Anti-Influenza Child's Face Mask is offered in two styles, Model: BF-200-3015A 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. Model: BF-200-2005A is a standard flat pleated mask. Both models comprise 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 being used in current legally marketed devices, and are not made with natural rubber latex. The outer active layer of the facemask is coated with a hydrophilic plastic containing citric acid. The second inner layer is treated with copper and zinc ions. Both layers inactivate	**Same:** Both predicate and subject devices use identical virus-inactivating materials in the first and second active layers. All four textile layers are identical in the predicate and subject masks. **Different:** The subject device is intended to be worn by children, and is appropriately smaller than this predicate, which is of an appropriate size to be used by adults.

	BioFriend™ BioMask™ Surgical Facemask Convex Model: BF-200-3013A and BF-200-2001A	**Innonix Anti-Influenza Child's Face Mask, Model: BF-200-3015A and BF-200-2005A**	**Comparison of Subject Device to Predicate**
		influenza viruses using different mechanisms of action.	
Intended Use	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 kill (inactivate) 99.99% of Influenza viruses (≥4-logs difference versus identical but untreated mask textiles) 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/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. There are two models: (1) Universal (BF-200-2001A) - is a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and an anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from Influenza infection. They are	The Innonix Anti-Influenza Child's Face Mask (Models BF-200-3015A and BF-200-2005A) is a single use, disposable device that is intended to be worn by children (recommended ages 5-10) to cover the nose and mouth to provide a barrier for the respiratory tract for microorganisms, body fluid and particulate materials. The mask is specifically for child or pediatric patients to provide protection for the respiratory tract. This face mask is recommended for use in a healthcare setting with appropriate adult supervision. The Innonix Anti-Influenza Child's Face Mask has hydrophilic plastic coating (active ingredient: citric acid 2%, a pH lowering agent) that rapidly absorbs aerosol droplets away from the outer surface of the mask and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%) that inactivate influenza viruses. The Innonix Anti-Influenza Child's Face Mask inactivated 99.99% of tested influenza viruses (≥4 log difference versus identical untreated control mask textiles) within five minutes of 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 (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),	**Same:** Both predicate and subject devices use identical virus-inactivating materials in the first and second active layers. All four textile layers are identical in the predicate and subject masks. **Different:** The subject device is intended to be worn by children, and is appropriately smaller. The predicate device is a medical device of an appropriate size to be used by adults.

	BioFriend™ BioMask™ Surgical Facemask Convex Model: BF-200-3013A and BF-200-2001A	**Innonix Anti-Influenza Child's Face Mask, Model: BF-200-3015A and BF-200-2005A**	**Comparison of Subject Device to Predicate**
	intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material.	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). The mask also inactivated >99.99% of Measles virus strain ATCC VR-24 and Coronavirus 229E strain ATCC VR-740 within one minute of contact with the surface of the facemask in laboratory in vitro tests. Correlation between in vitro results and any clinical event has not been tested.	
Outer (First) Layer	Spun-bond Polypropylene with Hydrophilic Plastic Coating	Spun-bond Polypropylene with Hydrophilic Plastic Coating	**Identical**
Second Layer	Spunlace Cellulose/Polyester Treated with Copper and Zinc	Spunlace Cellulose/Polyester Treated with Copper and Zinc	**Identical**
Third (Filtration) Layer	Melt-blown Polypropylene 18 g/m^2	Melt-blown Polypropylene: 18 g/m^2	**Identical**
Inner (Fourth) Layer	Spun-bond Polypropylene	Spun-bond Polypropylene	**Identical**
Fastening	Synthetic Elastic Ear Loops (not made with natural rubber latex)	Synthetic Elastic Ear Loops (not made with natural rubber latex)	**Identical**
Nose Strip	Malleable Aluminum Wire	Malleable Aluminum Wire	**Identical**
Bacterial Filtration (ASTM F2101)	99.9%	99.5%	**Identical**

	BioFriend™ BioMask™ Surgical Facemask Convex Model: BF-200-3013A and BF-200-2001A	**Innonix Anti-Influenza Child's Face Mask, Model: BF-200-3015A and BF-200-2005A**	**Comparison of Subject Device to Predicate**
Particulate Filtration (ASTM F2299)	99.7%	>99.5%	**Identical**
Differential Pressure (Delta P) (MIL M36954C)	2.6 mm H_2O/cm^2	2.5 mm H_2O/cm^2	**Identical**
Fluid Resistance (ASTM F2101)	Fluid Resistant 160mm Hg (>80 mm Hg)	Fluid Resistant 160mm Hg (>80 mm Hg)	**Identical**
Flammability (16 CFR 1610)	Class 1	Class 1	**Identical**
Irritation (ISO 10993)	Not an irritant	Not an irritant	**Identical**
Sensitization (ISO10993)	Not a sensitizer	Not a sensitizer	**Identical**
Extractables (ISO10993)	All extracted chemicals had margin of safety greater than 1	All extracted chemicals had margin of safety greater than 1	**Identical**

The Indication for Use and technological features of the Innonix Anti-Influenza Child's Face Mask are similar to the legally marketed predicate devices. The four textile layers are identical to those of the predicate mask, the Filligent BioFriend™ BioMask™Surgical Facemask, and the Innonix Anti-Influenza Child's Face Mask has child-appropriate size and other characteristics similar to the Prestige Ameritech Pediatric/Child's Face Mask. The Innonix Anti-Influenza Child's Face Mask and the respective predicate devices have similar intended uses and methods of operation.

4. Summary of Non-Clinical Testing

The Innonix Anti-Influenza Child's Face Mask was tested to verify the subject device met the standards listed below:

Test method	Purpose	Acceptance Criteria	Results
ISO 10993-10	Tests for irritation and skin sensitization	Not an irritant or sensitizer	Not an irritant or sensitizer
ISO 10993-18	Chemical characterization of materials	All extracted chemicals had margin of safety greater than 1	All extracted chemicals had margin of safety greater than 1
ASTM F2101	Bacterial Filtration Efficiency	>99%	99.5%
ASTM F2299	Sub-micron Particulate Filtration Efficiency	>99%	>99.5%
ASTM F1862	Fluid Penetration Resistance	Fluid Resistant (>80 mm Hg)	Fluid Resistant 160mm Hg
MIL-M-3654C	Breathing Resistance	<2.6 mm H_2O/cm^2	2.5 mm H_2O/cm^2
16 CFR 1610	Flammability Testing	Pass – Class 1	Pass – Class 1

EN71-1	Safety of Toys. Mechanical and Physical Properties	Pass	Pass
EN71-3	Chemical Testing (Migration of Certain Elements)	Pass	Pass
CPSC-CH-E1002-08	Total Lead Content Analysis	Pass	Pass
CPSC-CH-E1001-09.3	Phthalate Analysis DEHP, DBP, BBP, DINP, DnOP, and DnHP	Pass	Pass

The Innonix Anti-Influenza Child's Face Mask has been shown to conform to the following standards, practices, and guidance:

BIOCOMPATIBILITY

- ISO 10993-10, Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- ISO 10993-18, Biological evaluation of medical devices -- Part 18: Chemical characterization of materials

MECHANICAL PERFORMANCE

- ASTM F2100-11, Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F2101, Bacterial Filtration Efficiency
- ASTM F2299, Sub-micron Particulate Filtration Efficiency
- ASTM F1862, Fluid Penetration Resistance
- MIL-M-3654C, Breathing Resistance
- 16 CFR 1610, Flammability Testing

SAFETY TESTING FOR PEDIATRIC USE

- EN71-1, Safety of Toys. Mechanical and Physical Properties
- EN71-3, Chemical Testing (Migration of Certain Elements)
- CPSC-CH-E1002-08 Total Lead Content Analysis
- CPSC-CH-E1001-09.3 Phthalate Analysis DEHP, DBP, BBP, DINP, DnOP, and DnHP

In addition to the tests listed above that were performed on the subject device, a study of viricidal activity during simulated use was conducted to verify maintenance of the viricidal activity (≥4-logs versus identical but untreated mask textiles) of the mask textiles during repeated exposure to simulated nasal secretions and saliva over a period of 8 hours.

5. Discussion of Clinical and Performance Testing

Clinical testing is not needed for this device.

6. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices.