March 30, 2022

INTAI Technology Corp.
Dale Chang
Quality Management Representative of lmplants Business Unit
No. 9, Jingke Rd.,
Nantun Dist., Taichung 40852
Taiwan

Re: K210422
Trade/Device Name: INTAI Surgical Mask (non-sterile)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: March 9, 2022
Received: March 9, 2022

Dear Dale Chang:

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,

Bifeng Qian, M.D., Ph.D.
Acting Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210422

Device Name
INTAI Surgical Mask (non-sterile)

Indications for Use *(Describe)*
INTAI Surgical Mask is intended to be worn by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials. This is a single use, disposable device and provided non-sterile.

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 K210422

This summary regarding 510(k) information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitted By	INTAI Technology Corp. Registration No.3011187779 No.9 Jingke Rd., Nantun District, Taichung City, Taiwan, R.O.C. Tel. +886 4 23595336 Fax.+886 4 36013076
Contact Person	Kevin Wang
Date Prepared	March 25th, 2022
Device Name	INTAI Surgical Mask (non-sterile)
Classifications **Product Codes**	Class II, 21 CFR 878.4040 - Surgical apparel. FXX
Predicate Devices Information	K210218 SURGICAL MASK, Model Name:C015 Qingdao Hainuo Biological Engineering Co., Ltd
Material	Nonwoven (Polypropylene) fabric, melt blown polypropylene
Indication for Use	INTAI Surgical Mask is intended to be worn by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials. This is a single use, disposable device and provided non-sterile.
Device Description	The INTAI Surgical Mask is single use, three-layers, flat-pleated masks with ear loops, and nose clip. The inner and outer layers are made of Non-woven fabric (Polypropylene), and the middle filter layer is made of a melt blown fabric (Polypropylene). The ear loops welded are used to keep the mask close to the mouth and the nose. The ear loops are made of Nylon. The nose clip, which is made by plasticity material (HDPE), contained in masks is in the layers of the surgical mask to allow the users to fit the facemask around their nose. The surgical mask are provided in one color (blue), non-sterile and intended to be single use, disposable device.

Detailed information of the blue color Surgical Masks, please see the table below.

Product Model	Feature	Layers	Nose Clip	Ear loop	Colorant
9W001200 ASTM Level3	Blue 50 pcs/box	Outer: 35g Non-woven Middle: 25g Melt Blown Inner: 20g Non-woven	plasticity material (HDPE) CAS# 9002-88-4	Nylon CAS# 25038-54-4	Outer Layer: 147-14-8 980-26-7 84632-65-5 Ear loop: 12234-64-9
9W001201 ASTM Level3	Blue 30 pcs/box	Outer: 35g Non-woven Middle: 25g Melt Blown Inner: 20g Non-woven	plasticity material (HDPE) CAS# 9002-88-4	Nylon CAS# 25038-54-4	Outer Layer: 147-14-8 980-26-7 84632-65-5 Ear loop: 12234-64-9

Technological Characteristic Comparison

The proposed device is the same as or similar to the predicate device in term of the intended use, design and construction, and performance characteristics.

Table 1 General Comparison

Device	**Proposed Device**	**Predicate Device**	**Result**
510K #	K210422	K210218	
Name	INTAI Surgical Mask (non-sterile)	Surgical Mask	
Model	9W001200 9W001201	C015	
Classification	Class II Device, FXX (21CFR878.4040)	Class II Device, FXX (21CFR878.4040)	Identical
Intended use / Indications for Use	INTAI Surgical Mask is intended to be worn by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials. This is a single use, disposable device and provided non-sterile.	The Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The face mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is Identicala single use, disposable device(s), provided non-sterile.	Identical
Material			
Outer Layer	Non-woven fabric (Polypropylene)	Non-woven fabric (Polypropylene)	Identical
Middle Layer	Melt blown fabric (Polypropylene)	Melt blown fabric (Polypropylene)	Identical
Inner Layer	Non-woven fabric (Polypropylene)	Non-woven fabric (Polypropylene)	Identical
Nose Clip	PE plastic	Iron strip and Polypropylene	Different

Ear loop	Nylon	Polyester and Spandex	Similar
Mask Style	Flat Pleated	Flat Pleated	Identical
Color	Blue	Blue	Identical
Dimension (Length × Width)	175 ± 5 mm × 95 ± 5 mm	175 ± 5 mm × 95 ± 5 mm	Identical
OTC	Yes	Yes	Identical
Sterility	Non-Sterile	Non-Sterile	Identical
Use	Single use, disposable	Single use, disposable	Identical
Performance Testing (see Table 2)			
ASTM F2100 Level	Level 3	Level 3	Identical
Resistance to Penetration by Synthetic Blood	Meet ASTM F1862	Meet ASTM F1862	Identical
Sub-Micron Particle Filtration Efficiency	Meet ASTM F2299	Meet ASTM F2299	Identical
Differential Pressure	Meet EN 14683: 2019, Annex C	Meet EN 14683: 2019, Annex C	Identical
Bacterial Filtration Efficiency	Meet ASTM F2101	Meet ASTM F2101	Identical
Flammability	Meet 16 CFR 1610	Meet 16 CFR 1610	Identical
Biocompatibility	Non-cytotoxic, Non-sensitizing, nonirritating	Non-cytotoxic, Non-sensitizing, nonirritating	Identical

Table 2 Comparison of Performance testing

Item	**Proposed device (K210422)** Blue	**Predicate device (K210218)**	**Acceptance criteria (Level 3)**	**Result**
Resistance to Penetration by Synthetic Blood	Achieve a 4% AQL at 160mmHg	Achieve a 4% AQL at 160mmHg	Achieve a 4% AQL (29 out of 32 pass at 160mmHg)	Pass
Sub-Micron Particle Filtration Efficiency	≥98%	≥98%	≥98%	Pass
Differential Pressure	<6.0	<6.0	<6.0	Pass
Bacterial Filtration Efficiency	≥98%	≥98%	≥98%	Pass
Flammability	Class 1	Class 1	Class 1	Pass

Summary of Non-Clinical Test

Non-Clinical tests were conducted to verify that the proposed device met all design specifications as was same to the predicate device. The test results demonstrated that the proposed device complies with the following standards and the requirements stated in the Guidance for Industry and FDA staff: ***Surgical Masks - Premarket Notification [510(K)] Submission*** issued on March 5, 2004:

- ISO 10993-5: 2009 Biological Evaluation of Medical Devices–Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation of Medical Devices–Part 10: Tests For Irritation And Skin Sensitization
- ASTM F2100, Standard Specification for Performance of Materials Used In Medical Face Masks
- ASTM F1862, Standard Test Method for Resistance of Medical Face Masks To Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume At A Known Velocity)
- EN 14683, Medical Face Masks–Requirements and Test Methods
- ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using A Biological Aerosol of Staphylococcus Aureus
- ASTM F2299, Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particulated using latex spheres
- 16 CFR 1610, Standard for the Flammability of clothing textiles

Test Method	**Purpose** **Applied Standards**	**Acceptance criteria**	**Results**
Bacterial Filtration Efficiency (BFE) Testing	Determine the bacterial filtration efficiency ASTM F2100 9.1 ASTM F2101-2019	≥98 %	PASS
Differential Pressure Testing	Determine breathing resistance or differential pressure ASTM F2100 9.2 EN 14683:2019 Annex C	<6.0 mm H_2O/cm^2	PASS
Sub-micron particulate filtration	Determine particulate filtration efficiency	≥98 %	PASS

(PFE) efficiency Testing	ASTM F2100 9.3 ASTM F2299-2017		
Synthetic blood penetration Testing	Determine synthetic blood penetration resistance ASTM F2100 9.4 ASTM F1862-2017	160 mmHg	PASS
Flammability Testing	Determine flammability ASTM F2100 9.5 CPSC 16 CFR 1610-2008	Did Not Ignite (DNI)	PASS
In Vitro Cytotoxicity Test	The aim was to investigate the cytotoxic effect ISO 10993-5	No cell lysis, no reduction of cell growth	PASS
Skin Irritation Test	Evaluate the possibility of irritant reaction ISO 10993-10	Non-irritant	PASS
Skin Sensitization Test	Evaluate the possibility of delayed hypersensitivity ISO 10993-10	No visible change	PASS

Summary of Clinical Test	Clinical testing is not required.
Conclusion	The conclusion drawn from the nonclinical tests demonstrate that the devices are as safe, as effective, and perform as well as or better than the legally marketed predicate device, K210218Qingdao Hainuo Biological Engineering Co., Ltd Surgical Mask.