January 25, 2022

Asia Dynamics Inc., d/b/a ADI Medical
Timothy Kania
Official Correspondant
Mdi Consultants Inc.
55 Northen Blvd, Suite 200
Great Neck, New York 11021

Re: K213347
Trade/Device Name: ADI Medical Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 27, 2021
Received: December 29, 2021

Dear Timothy Kania:

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 Clarence W. Murray III, PhD
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)*
K213347

Device Name
ADI Medical Surgical Face Masks

Indications for Use *(Describe)*
ADI Medical Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material.
These face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids.
This is a single use, disposable device(s), 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.

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

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510(k) SUMMARY

1. Submitter's Identification:

Applicant: Asia Dynamics Inc., d/b/a ADI Medical
Address: 1565 South Shields Drive Waukegan, IL 60085
Contact Person: Jonathan Zhu
Tel: (847)-688-9968
Email: Jon@adimedical.com

Date Summary Prepared: December 27, 2021

Official Correspondent: Mr. Tim Kania
Mdi Consultants, Inc.
Address: 55 Northern Blvd. Suite 200, Great Neck, NY, United States
Tel: 732-796-4565
Email: tim@mdiconsultants.com

2. Name of the Device:

Proprietary Name: ADI Medical Surgical Face Mask
Classification Name: Mask, Surgical
Common Name: Surgical Mask
Regulatory Class: II
Product Code: FXX
Regulation Name: Surgical Apparel
Regulation Number: 878.4040
Review Panel: General Hospital

3. Information for the 510(k) Cleared Device (Predicate Device):

Disposable Medical Face Mask, K202513

Surgical Face Mask

Shenzhen Jinko Industrial Co., Ltd..

No reference devices were used in this submission.

4. Device Description:

The ADI Medical Surgical Face Masks are single use, three-layer, flat –folded masks with ear loops and nose clamp. The ADI Medical Surgical Face Masks are manufactured with three layers, the inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter. The ear loops are held in place over the users' mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are not made with natural rubber latex. The nose clamp in the layers of facemask is to allow the user to fit the facemask around their nose, which is made of malleable polyethylene wire. ADI Medical Surgical Face Masks will be

provided in blue. ADI Medical Surgical Face Masks are sold non-sterile and are intended to be single use, disposable devices.

5. Indications for Use:

ADI Medical Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

6. Technological Characteristics Comparison:

Table 1: Comparison to Predicate Device

Device		Proposed Device	Predicate Device	Result
Manufacturer		Asia Dynamics Inc., d/b/a ADI Medical	Shenzhen Jinko Industrial Co., Ltd.	-
510K number		K213347	K202513	-
Model Name		ADI Medical Surgical Face Mask	Disposable Medical Face Mask	Similar
Model No.		76120	FM-04	-
Classification		Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Intend use		ADI Medical Surgical Masks are intended to be worn to protect both the patientand healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	The Medical Masks are intended to be worn to protect both the patientand healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure of thewearer to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	Same
Model		Ear Loops, Flat Pleated, 3 layers	Ear Loops, Flat Pleated, 3 layers	Same
Material	**Outer facing layer**	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner Facing Layer	Spun-bond polypropylene	Spun-bond polypropylene	Same

	Nose Clamp	Malleable polypropylene with steel wire	Malleable polypropylene with steel wire	Same
	Ear Loops	Polyester, Spandex	Polyester, Spandex	Same
Color		Blue CAS#147-14-8	Variety (include blue)	Similar
Dimension (Length)		175±2.5mm	175±8mm	Similar
Dimension (Width)		95±2.5mm	95+4.5 mm	Similar
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
Use		Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100 Level		Level 2	Level 2	Same
Biocompatibility (ISO10993)		Non-Cytotoxic, Non-Sensitizing,Non-Irritating	Non-Cytotoxic, Non-Sensitizing, Non-Irritating	Same

7.Summary of Non-Clinical Tests:

The following testing was conducted to demonstrate that the subject device (3 non-consecutive lots with each lot containing 32 samples) met the acceptance criteria and specification of the standard shown below.

Table 2: Performance testing

Standard	Results of tests on subject device	Pass Criteria	Results
Fluid Resistance PerformanceASTM F1862	94 out of 96 pass at 120 mmHg, 3 non-consecutive lots tested	29 out of 32 pass at 120 mmHg	PASS
Particulate Filtration Efficiency ASTM F2299	96 out of 96 pass Average: 99.47% ≥ 98%	≥ 98%	PASS
Bacterial Filtration Efficiency ASTM F2101	96 out of 96 pass Average: 99.48% ≥98%	≥ 98%	PASS
Differential Pressure (Delta P) EN 14683 Annex C	96 out of 96 pass Average: 3.52 < 5.0mmH_2O/cm^2	< 6.0mmH_2O/cm^2	PASS
Flammability 16 CFR 1610	Class 1	Class 1	PASS

Table 3: Biocompatibility Testing

Item	**Proposed device**	**Acceptance Criteria**	**Result**
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic.	Non-Cytotoxic	PASS
Irritation	Under the conditions of the study, the device is non-irritating.	Non-Irritating	PASS
Sensitization	Under the conditions of the study, the device is non-sensitizing	Non-Sensitizing	PASS

8.Discussion of Clinical Tests Performed:

No clinical study is included in this submission.

9.Conclusions:

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission K213347, the ADI Medical Surgical Masks, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K202513.