July 17, 2023

Durio PPE SDN BHD
℅ Ms. Sarah Fitzgerald
Senior Consultant, Regulatory and Quality Affairs
Emergo Global Consulting, LLC
2500 Bee Caves Rd., Bldg. 1, Ste. 300
Austin, Texas 78746

Re: K230395
Trade/Device Name: Durio Surgical Face Mask, Models 501 (3-ply, blue) and 545 (4-ply,blue)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 12, 2023
Received: June 12, 2023

Dear Ms. Fitzgerald:

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,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K230395

Device Name
Durio Surgical Face Mask

Indications for Use *(Describe)*
Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It is intended for use in infection control practices to reduce the potential exposure 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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K230395: 510(k) Summary

Durio Surgical Face Masks:

Model 501 (3-ply, blue) and Model 545 (4-ply,blue)

1. Submission Sponsor

Durio PPE SDN BHD
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Title: Deputy General Manager

2. Submission Correspondent

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Contact: Sarah Marie Fitzgerald
Title: Senior Consultant, Regulatory and Quality Affairs

3. Date Prepared

June 16, 2023

4. Device Identification

Trade/Proprietary Name:	Durio Surgical Face Mask, Models 501 (3-ply, blue) and 545 (4-ply,blue)
Common/Usual Name:	Surgical Mask
Classification Name:	Surgical apparel
Regulation Number:	21 CFR 878.4040
Product Code:	FXX
Class:	II
Classification Panel:	General Hospital

5. Legally Marketed Predicate and Reference Device(s)

Device name:	Surgical Mask
510(k) number:	K212344
Type:	Predicate

Manufacturer:	Xiantao Dingcheng Non-Woven Product Co., Ltd.
Device name:	CAREWE Surgical Face Mask Models N001-AW, N002-AW, and N003-AW
510(k) number:	K203078
Type:	Reference
Manufacturer:	Guangdong Kaidi Garments Co., Ltd.

6. Indication for Use Statement

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

7. Device Description

The Durio Surgical Face Mask is a non-sterile, single use, flat-pleated style surgical mask with ear loops and nose piece.

The Durio Surgical Face Mask is available in three or four ply models. In all cases, the inner and outer layers of the Durio Surgical Face Mask are made of non-woven spunbond polypropylene (PP). The outer layer repels fluid and droplets. The middle layer is made of non-woven melt blown PP fabric for filtration by mechanical blocking and electrostatic attraction. For the four-ply model, there is an additional middle layer made of non-woven spunbound PP. The ear loops are made of polyester covered spandex yarn. The elastic ear loops pull inward from welding on the outer layer to reduce gaps as the side between the face and mask. The nose strip is made of zinc electro galvanized steel wire allowing adjustability and to let it stand fixed for better fit.

The Durio Surgical Face Mask is provided in blue. The device is not made from any natural rubber latex.

8. Substantial Equivalence Discussion

The following table compares the Durio Surgical Face Mask to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 5A – Comparison of Characteristics

Attribute	Subject Durio Surgical Face Mask	Predicate Surgical Mask (K212344)	Comparison
Product Code	FXX	FXX	Same
Regulation	21 CFR 878.4040	21 CFR 878.4040	Same
Indications for Use	Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms,	Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms,	Same

Attribute	Subject Durio Surgical Face Mask	Predicate Surgical Mask (K212344)	Comparison
	body fluids and particulate material. It is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non sterile.	body fluids, and particulate material. It is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non sterile.	
Mechanism of Action	Physical barrier	Physical barrier	Same
Single-Use	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Same
Composite	Flat Pleated, 3 or 4 Layers	Flat Pleated, 3 Layers	Equivalent* Same as reference K203078
Materials: Outer	Spunbond Polypropylene (SBPP)	Spunbond Polypropylene (SBPP)	Same
Materials: Middle	Melt Blown Polypropylene (MBPP)	Melt Blown Polypropylene (MBPP)	Same
Materials: 4th Layer	None or MBPP	None	Equivalent* Same as reference K203078
Materials: Inner	Hydrophilic Spunbond Polypropylene (HPP)	Spunbond Polypropylene (SBPP)	Equivalent*
Materials: Nose-Piece	Galvanized steel wire, flexible	Galvanized iron wire, flexible	Equivalent*
Materials: Earloop	Polyester and Spandex	Polyester and Spandex	Same
Dimensions	175mm x 95mm	175mm x 95mm	Same
Color	Blue	Blue	Same
OTC Use	Yes	Yes	Same
ASTM F2100 Level	Level 2 (3-Ply) Level 3 (4-Ply)	Level 3	Equivalent**
Biocompatibility	Biocompatible per ISO 10993 Series Testing	Biocompatible per ISO 10993 Series Testing	Same

* The devices have minor differences in materials. The differences do not raise new or different questions related to the safety or effectiveness of the device, and performance and biocompatibility evaluation and testing addresses these differences; therefore the devices are substantially equivalent.

** Testing was conducted within alignment with the labeled protection level; therefore the devices are substantially equivalent.

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of the Durio Surgical Face Mask and to show substantial equivalence to the predicate device, Durio completed various bench performance tests. No animal or clinical testing was required. Results confirm that the design inputs and performance specification of the device are met. Durio Surgical Face Masks passed the testing in accordance with internal requirements

and standards as shown below, supporting its safety, effectiveness, and substantial equivalence to the predicate device.

- Biocompatibility Testing (Cytotoxicity, Irritation, Sensitization) per ISO 10993-5 and ISO 10993-10
- Bacterial Filtration Efficiency (BFE) per ASTM F2101-19
- Sub-micron Particulate Efficiency (PFE) per ASTM F2100-19
- Resistance to Penetration by Synthetic Blood per ASTM F1862/F1862M-17
- Differential Pressure per ASTM F2100-19
- Flame Spread per 16 CFR 1610 (Class 1)
- Shipping Performance per ASTM D4169-16

10. Clinical Performance Data

No animal or clinical testing was required.

11. Statement of Substantial Equivalence

The Durio Surgical Face Mask has the same indications for use as the Surgical Mask (K212344). Any minor differences in the technological characteristics of the subject device when compared to the predicate device have been successfully evaluated through appropriate safety and performance testing which demonstrates that the subject device, when compared to the predicate device, does not raise any new questions of safety and effectiveness. Therefore, the Durio Surgical Face Mask has been determined to be substantially equivalent to predicate Surgical Mask (K212344).