March 5, 2021

BDC Dental Corporation Ltd.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K203425
Trade/Device Name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 19, 2021
Received: February 23, 2021

Dear Prithul Bom:

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 Ryan Ortega, 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)*
K203425

Device Name
Surgical Mask

Indications for Use *(Describe)*
The surgical masks are intended to be worn by personnel during medical and surgical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluids and particulate material. The mask is a single use, disposable device, 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

Date of Summary Prepared: March 3, 2021

510K Number: K203425

Establishment Registration Number (FEI): 3006985142

Applicant: BDC Dental Corporation Ltd.
Part 3, No.1 Guanchong Section, Shilian,
Shiqi Town, Panyu District, Guangzhou,
Guangdong CN 511450

Primary Contact: Jack Yang
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Device Name: Surgical Mask
Device Classification Name: Mask, Surgical
Trade name: Surgical Mask
Classification: Class II 21 CFR 878.4040
Regulation Medical Specialty: General and Plastic Surgery
Product Code: FXX

Predicate Device: K051291 - A.R. Medicom Inc.

Indications for Use

The surgical masks are intended to be worn by personnel during medical and surgical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluids and particulate material. The mask is a single use, disposable device, provided nonsterile.

Device Description

The Surgical Masks, Model IIR, are non-sterile, single use, three-layers, flat-pleated style with ear loop and nose piece.

- The inner and outer layers of the Surgical Mask are made of Non-woven Spunbond Polypropylene for protection against fluid penetration that will not lint, teat or shred.
- The middle layer is made of highest quality Melt Blown Polypropylene Filter for optimal filtration and breathability, meeting ASTM Level 3 performance requirements.
- The sonically sealed ear loops are made of Polyester and Spandex to secure the mask over the user's face and mouth. They fit loosely and are attached to the outside of the mask to eliminate irritation.
- The adjustable nose piece is made of Aluminum forms strong seal for protection.

The Surgical Masks will be provided in Blue. The device is not made from any natural rubber latex.

Comparison of Technological Characteristics with the Predicate Device

Features	Subject Device	Predicate Device	Comparison
Manufacturer	**BDC Dental Corporation Ltd.**	**A.R. Medicom Inc.**	NA
Device Name	Surgical Mask	Non-Sterile Surgical Mask	NA
Model	IIR	Safe Mask SofSkin-2087	NA
510K	K203425	K051291	NA
Classification	Class II Device, FXX (21 CFR878.4040)	Class II , FXX (21 CFR878.4040)	Same
Intended Use	The surgical masks are intended to be worn by personnel during medical and surgical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluids and particulate material. The mask is a single use, disposable device, provided nonsterile.	The medical/surgical mask listed below are indicated as a protective nose and mouth covering for health care workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of microorganism, body fluid, and particulate transfer.	Similar
Color	Blue	Blue	Same
Disposable	Yes	Yes	Same

Features	Subject Device			Predicate Device			Comparison
Materials	Mask Body	Outer Material	Spunbond Polypropylene (SBPP)	Mask Body	Outer Material	Spunbond Polypropylene (SBPP)	Same
		Filter Layer	Melt Blown Polypropylene (MBPP)		Filter Layer	Melt Blown Polypropylene (MBPP)	
		Inner Layer	Spunbond Polypropylene (SBPP)		Inner Layer	Spunbond Polypropylene (SBPP)	
	Nose-piece	Aluminum		Nose-piece	Aluminum		
	Earloop	Polyester and Spandex		Earloop	Polyester and Spandex		
Earloop Style	Flat knitted earloop			Flat knitted earloop			
Dimension	Body Size	Length	170mm	Body Size	Length	175 mm (6 ⅞")	Difference
		Width	95mm		Width	90,5 mm (3 ½")	
	Earloop	Length	165mm	Earloop	Length	165 mm (6 ½")	
		Width	3mm		Width	3mm	
	Pleat Depth	14mm		Pleat Depth	14 mm (⅝")		
	Length of Nose-piece	80mm		Length of Nose-piece	120 mm (4 ¾")		

Performance	Subject Device		Predicate Device			Comparison
ASTM Requirements	ASTM LEVEL 3 Test Criteria	ASTM LEVEL 3 Test Results	ASTM LEVEL 1	ASTM LEVEL 2	ASTM LEVEL 3	NA
Bacterial filtration efficiency(BFE)	≥98%	LOT# KZ200708005 32/32 PASSED AVERAGE 99.9% LOT# KZ200801002 32/32 PASSED AVERAGE 99.9% LOT# KZ200905006 32/32 PASSED AVERAGE 99.9%	≥95%	≥98%	≥98%	Similar
Sub-micron particulate efficiency at 0.1 μm (PFE)	≥98%	LOT# KZ200708005 32/32 PASSED AVERAGE 99.74% LOT# KZ200801002 32/32 PASSED AVERAGE 99.81% LOT# KZ200905006 32/32 PASSED AVERAGE 99.86%	≥95%	≥98%	≥98%	

Resistant to penetration by synthetic blood	@160 mm Hg	LOT# KZ200708005 32/32 PASSED No Penetration at 160 mmHg LOT # KZ200801002 32/32 PASSED No Penetration at 160 mmHg LOT# KZ200905006 32/32 PASSED No Penetration at 160 mmHg	@80 mm Hg	@120 mm Hg	@160 mm Hg	
Differential Pressure (△P)	< 6.0 mm H_2O/cm^2	LOT# KZ200708005 32/32 PASSED AVERAGE 2.69 LOT# KZ200801002 32/32 PASSED AVERAGE 3.28 LOT# KZ200905006 32/32 PASSED AVERAGE 2.63	< 4.0 mm H_2O/cm^2	< 5.0 mm H_2O/cm^2	< 5.0 mm H_2O/cm^2	
Flame Spread	Class I	LOT# KZ200708005 32/32 PASSED DNI LOT# KZ200801002 32/32 PASSED DNI LOT# KZ200905006 32/32 PASSED DNI	Class 1			Same
Biocompatibility	ISO10993-5 and ISO10993-10; Under the conditions of the studies employed, the device is non-cytotoxic, non-sensitizing, and non-irritating.		ISO10993-5 and ISO10993-10; Under the conditions of the studies employed, the device is non-cytotoxic, non-sensitizing, and non-irritating.			Same

Based on the comparison data aforementioned, the minor difference of dimension (length, width), length of nose piece and the differential pressure will not impact the safe and effectiveness of subjective device since the material, the function of the nose piece and major performance remains the same as the predicate device.

Non-clinical Test Performed

The design and manufacturing process have been validated in accordance with standards and requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks –Premarket Notification [510(k)].

Table 1 of Conformity to Standards

Standards	Standard Name
[Rec# 6-425] ASTM F2100-20	Standard Specification for Performance of Materials Used in the Medical Face Masks
[Rec#6-427] ASTM F2101-19	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
[Rec#6-406] ASTM F1862 F1862M-17	Standard Test Method for Resistance of Medical Face Masks to penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
ASTM F2299 F2299M-17	Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
[Rec#2-220] ISO10993-1	Biological evaluation of medical devices - Part 1: Evaluation and Testing.
[Rec#2-245] ISO10993-5	Biological evaluation of medical devices -Part 5: Tests for in vitro cytotoxicity.
[Rec#2-174] ISO10993-10	Biological evaluation of medical devices -Part 10: Tests for irritation and delayed-type hypersensitivity.

Table 2 of Performance Testing-Bench

ASTM Requirements	Acceptance Criteria- ASTM Level 3	Result
Bacterial filtration efficiency(BFE) ASTM F2101-19	≥98%	Pass
Sub-micron particulate efficiency at 0.1 µm (PFE) ASTM F2299	≥98%	Pass
Resistant to penetration by synthetic blood ASTM F1862	@160 mm Hg	Pass
Differential Pressure (△P) EN 14683:2019+AC:2019	< 6.0 mm H_2O/cm^2	Pass
Flame Spread 16 CFR part 1610(a)	Class 1	Pass

Table 3 of Biocompatibility Testing

Item	Proposed Device	Acceptance Criteria	Result
Cytotoxicity ISO 10993-5	Under the conditions of the study, the device is non-cytotoxic.	Non-Cytotoxic	Pass
Irritation ISO 10993-10	Under the conditions of the study, the device is non-irritating	Non-Irritating	Pass
Sensitization ISO 10993-5	Under the conditions of the study, the device is non-sensitizing	Non-Sensitizing	Pass

Summary of clinical performance data:

No clinical data is required for this device. There are no major safety concerns.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device [K203425] is as safe, as effective, and performs as well as or better than the legally marketed predicate device [K051291]