December 1, 2020

Base4 Group, Inc.
% Thomas Knott
Senior Regulatory Advisor
Benjamin L. England and Associates, LLC
810 Landmark Dr, Suite 126
Glen Burnie, Maryland 21061

Re: K202069
Trade/Device Name: BASE4 Disposable Medical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 2, 2020
Received: November 2, 2020

Dear Thomas Knott:

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 CAPT Elizabeth Claverie, M.S.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202069

Device Name
Surgical Face Mask

Indications for Use *(Describe)*
When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and airborne particles. This device is non-sterile and for single use only.

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: November 25, 2020
510(k) Number: K202069

Submitted By:	Benjamin L. England And Associates, LLC
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On Behalf of:	BASE4 Group, Inc.
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E-Mail:	Jon@ebase4.com
Contact:	Jon Filipski

1. Regulatory Information

Proprietary Name:	BASE4 Disposable Medical Mask (NB Green2020-12; Model Number is 07787)
Classification Name:	Surgical Face Mask, Apparel
Common Name:	Surgical face mask
Classification:	Class II
Product Code:	FXX
Panel	General Surgery Devices
Regulation:	21 CFR 878.4040

2. Predicate Device

510(k) Number:	K200847
Device Name:	Mask, Surgical Apparel

3. Indications for Use

When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and airborne particles. This device is non-sterile and for single use only.

4. Device Description

The surgical face mask is a non-sterile, single use, three-layer, flat, pleated style with ear loops and a nose piece. The outer and inner layers are spunbond polypropylene, and the middle layer consists of melt-blown polypropylene filter. Each mask is secured to the face with ear loops with a nosepiece to conform the mask to the shape of the nose.

5. Summary of Comparison and Technological Characteristics

Table 1 - General Comparison

CLASSIFICATION INFORMATION			
510(k) Number	K202069	K200847	N/A
Manufacturer	Ningbo Green Textile Co., Ltd	Mexpo International, Inc.	N/A
Common Name	Surgical Face Mask	Surgical Face Mask	Same
Product Code	FXX	FXX	Same
Classification	Class II	Class II	Same
Regulation	21 CFR 878.4040	21 CFR 878.4040	Same
Intended use	When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and airborne particles. This device is non-sterile and for single use only	When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and airborne particles. This device is non-sterile and for single use only	Same
Model	Three ply, flat pleated, ear loops	3 Ply, Ear Loops, Flat-Pleated Style	Same
Tensile Strength	10 – 15 N	N/A	N/A

MATERIALS			
Outer Layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
Middle Layer	Melt Blown Polypropylene Filter	Melt Blown Polypropylene Filter	Same
Inner Layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
Nose Piece	Galvanized wire coated by PVC	Single Galvanize Wire, Coated By PE	Similar
Ear Loops	70% polyester; 30% spandex	not made with natural rubber latex	Unknown
Color	Blue outer layer	White	Differs
Width	95 mm = 9.5 cm	9.0cm ± 0.5cm	Same
Length	175 mm = 17.5 cm	17.5cm ± 0.5cm	Same
OTC Use?	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Single Use?	Yes	Yes	Same
ASTM F2100	Level 2	Level 2	Same

ASTM F1862 Fluid Resistance Performance	31 out of 32 pass at 80 mm Hg 30 out of 32 pass at 120 mm Hg	30 Out of 32 pass at 120 mm Hg	Same
ASTM F2299 Particulate Filtration Efficiency	98.8%	99.9%	Both Pass Similar
ASTM F2101 Bacterial Filtration Efficiency	> 99.9%	> 99.9%	Same
Differential Pressure (Delta P) MIL- M-36954C	4.4 mmH_20/cm^2	3.0 mmH_20/cm^2	Both Pass Similar
Flammability 16 CFR 1610	Class 1	Class 1	Same
Biocompatibility Testing	Non-Cytotoxic, Non-Sensitizing, Non-Irritating	Non-Cytotoxic, Non-Sensitizing, Non-Irritating	Same

The outer layer of the subject mask is colored blue, and the predicate device is white. Otherwise, they are the same material, polypropylene. The outer layer does not contact the patient's skin and therefore presents minimal risk to the health of the user.

The nose piece for both devices is galvanized wire. The subject device is covered by PVC and the predicate device is covered by PE. However, neither material will contact the user's skin so there is no difference in risk to the health of the user.

The 510(k) Summary for the predicate device does not show the material for the ear loops. Therefore, no comparison can be made.

The Particulate Filtration Efficiency and Differential Pressures are similar for both masks and pass the specification required by ASTM F2100 for a level 2 mask.

6. Non-clinical Tests Performed on the Proposed Device

The proposed device was tested and conformed to 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.

- ASTM F2100: Standard Specification for Performance of Materials Used in Medical Face Masks
- 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-03: Determining the Initial Efficiency of Materials Used in Medical Face Masks to the Penetration of Particulates Using Latex Spheres
- ASTM F2101: Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus*
- MIL- M-36954C: Medical face masks - Requirements and test methods, Annex C

- 16 CFR 1610 - CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles.
- ISO 10993-5: Biological evaluation of medical devices-Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10: Biological evaluation of medical devices Part 10:Tests for irritation and skin sensitization

Table 2 - Performance Testing

Test	Proposed Device	Acceptance Criteria	Result
Fluid Resistance Performance ASTM F1862	31 out of 32 pass at 80 mm Hg 30 out of 32 pass at 120 mm Hg	29 out of 32 pass at 120 mm Hg	Pass Level 2
Particulate Filtration Efficiency ASTM F2299	98.8%	≥ 98%	Pass
Bacterial Filtration Efficiency ASTM F2101	> 99.9%	≥ 98%	Pass
Differential Pressure (Delta P) MIL- M-36954C	4.4 mmH_20/cm^2	< 5.0 mm H_20/cm^2	Pass
Flammability 16 CFR 1610	Class 1	Class 1	Pass

Table 3 - Biocompatibility Testing

Item	Proposed Device	Acceptance Criteria	Result
Results	Non-Cytotoxic, Non-Sensitizing, Non-Irritating	Non-Cytotoxic, Non-Sensitizing, Non-Irritating	Pass

7. Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

****END OF 510(k) SUMMARY*****