April 14, 2021

Young Dental Manufacturing Co. 1, LLC
Jose Espino, Official Correspondent
13705 Shoreline Court East
Earth City, Missouri 63045

Re: K201127
Trade/Device Name: DEFEND Ear-loop Face Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 6, 2021
Received: April 8, 2021

Dear Jose Espino:

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,

Ryan Ortega -S

Ryan Ortega, PhD.
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)*
K201127

Device Name
DEFEND Ear-loop Face Masks

Indications for Use *(Describe)*
DEFEND Ear-loop Face Masks are intended to be worn to protect both the patient and healthcare professional 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 to blood and body fluids. This is a single use, disposable device, provided non-sterile.

Level 3 Model: MK-7300

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

As required by the Safe Medical Devices Act (SMDA) of 1990 and in accordance with 21 CFR § 807.93, 510(k) summary is provided.

DATE: April 2, 2021

510(k) NUMBER: K201127

I. SUBMITTER

Young Dental Manufacturing Co 1, LLC.
13705 Shoreline Ct. E.
Earth City, MO 63045

Tel: 847-458-5829 ext. 2829
Email: jespino@younginnovations.com

II. OFFICIAL CORRESPONDENCE/CONTACT PERSON

Jose Espino
13705 Shoreline Ct. E.
Earth City, MO 63045

Tel: 847-458-5829 ext. 2829
Email: jespino@younginnovations.com

III. 510(K) PREPARER

Brian Prange
13705 Shoreline Ct. E.
Earth City, MO 63045

Tel: 314-372-8054
Email: bprange@younginnovations.com

IV. DEVICE

Brand Name of Device: DEFEND Ear-Loop Face Masks
Common or Usual Name: Surgical Mask
Classification Name: Mask, Surgical
Regulation: 21 CFR 872.4040
Device Classification: Class: II

Product Code: FXX

V. PREDICATE DEVICE

Trade Name: Surgical Masks (Ear loop and Tie-on)
Common Name: Surgical Mask
510(k) Number: K160269 (Decision Date: September 6, 2016)
Manufacturer: San-M Package Co., LTD.

VI. DEVICE DESCRIPTION

The DEFEND Ear-Loop Face Masks are comprised of four layers of nonwoven materials ultrasonically welded together along the edges with ear loops ultrasonically welded to the sides. The four layers include an outer layer (faces outward when worn), filtration layer, middle layer, and inner layer (faces the user).

The materials used in this mask meet the performance requirements for Level 3 stated in ASTM F2100 -19 Performance of Materials Used in Medical Face Masks. The mask is secured to the face with ear loops. The mask also includes a form-fitting pliable nose piece to improve fit and reduce gaps for maximum protection.

The DEFEND Ear-Loop Face Masks will be available in ASTM Level 3 in blue. Table 1 lists the Model number of the masks that will be available.

Table 1. DEFEND Ear-Loop Face Masks Model Number

Model Number	ASTM Level	Color
MK-7300	Level 3	Blue

VII. INDICATIONS FOR USE

The DEFEND Ear-Loop Face Masks are intended to be worn to protect both the patient and healthcare professional 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 to blood and body fluids. This is a single use, disposable device, provided non-sterile.

VIII. SUBSTANTIAL EQUIVALENCE (SE) COMPARISON

Table 2. Device Comparison (Similarities and Differences)

Product Comparison – Similarities and Differences			
Characteristic	**Proposed Device**	**San-M Package Co., LTD., Surgical Face Masks (Ear loops and Tie-on)**	**Results**
Manufacturer	Young Innovations	San-M Package Co., Ltd.	
510(k) Number	K201127	K160269	
Class	Class II	Class II	Same
Regulation Number	21 CFR 872.4040	21 CFR 872.4040	Same
Intended Use / Indications for Use	The DEFEND Ear-Loop Face Masks are intended to be worn to protect both the patient and healthcare professional 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 to blood and body fluids. This is a single use, disposable device, provided non-sterile.	The surgical face 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 to blood and body fluids. This is a single-use, disposable device, provided non-sterile.	Same
Product Code	FXX	FXX	Same
Use	OTC	OTC	Same
Length of Main body	175 mm ± 5 mm	175 mm ± 5 mm or 180 mm ± 5 mm	Same
Width of Main body	95 mm ± 5 mm	90 mm ± 5 mm	Similar
Mask Style	Flat-pleated	Flat-Pleated	Same
Sterility	Non-Sterile	Non-Sterile	Same
Single Use	Yes	Yes	Same
Colors	Blue	White or Blue	Similar

Outer Material		Spunbond Polypropylene	Polypropylene	Same
Filter Material		Meltblown Polypropylene Fluid Resistant Polypropylene Film-Blue	Polypropylene spunbond Polypropylene meltblown	Same
Inner Material		Spunbond Polypropylene	Polyethylene	Similar
Ear loops		Polyester	Polyester, polyurethane	Same
Nose piece		Steel wire	Polyethylene coated steel wire	Similar
Performance Testing (ASTM F2100-11)				
Fluid Resistance (ASTM F1862)	Level 3 (@ 160 mmHg)	Pass @ 160 mmHg	Pass at 160 mmHg	Same
Particulate Filtration Efficiency (ASTM F2299)	Level 3 (≥ 98%)	Pass @ 99.5%	Pass at 99.7%	Same
Bacterial Filtration Efficiency (ASTM F2101)	Level 3 (≥ 98%)	Pass @ > 99%	Pass at > 99%	Same
Differential Pressure (EN 14683:2019, Annex C and MIL-M-36954C)	Level 3 (< 6.0)	Pass @ 3.4-4.0	Pass at 2.5 mmH_2O/cm^2	Same
Flammability (16 CFR 1610)	Level 3 (Class 1)	Class 1	Class 1	Same
Cytotoxicity ISO 10993-5		Under the conditions of the study, the subject device was non-cytotoxic.	Under the conditions of the study the subject device was non-cytotoxic.	Same
Irritation ISO 10993-10		Under the conditions of the study, the subject device was non-irritating.	Under the conditions of the study, the subject device was non-irritating.	Same
Sensitization ISO 10993-10		Under the conditions of the study, the subject device was non-sensitizing.	Under the conditions of the study, the subject device was non-sensitizing.	Same

As indicated in Table 2, all relevant comparison items are very similar, and do not exhibit any changes that would impact intended use or the user experience.

IX. SUMMARY OF NON-CLINICAL PERFORMANCE DATA

The DEFEND Ear-Loop Face Masks have been tested according to the Guidance for Industry and FDA Staff: *Surgical Masks-Premarket Notifications [510(k)] Submissions,* issued March 5, 2004. This includes performance testing according to ASTM F2100. See Table 3 for a testing summary.

Table 3. Summary of ASTM F2100 Testing

Methodology	Purpose	Acceptance Criteria (AQL = 4.0%)	Results
ASTM F1862	Determine synthetic blood penetration resistance	29/32 pass at 160 mmHg	32/32 Pass per lot at 160 mmHg
ASTM F2101	Determine the bacterial filtration efficiency	≥ 98%	32/32 Pass per lot, Average = 99.8%
ASTM F2299	Determine sub-micron particulate filtration efficiency	≥ 98%	32/32 Pass per lot, Average = 99.7%
MIL-M-36954C or EN 14683 Annex C	Determine breathing resistance or differential pressure	< 6.0 mm H_2O/cm^2	32/32 Pass per lot, 3.4 – 4.0 mm H_20/cm^2
16 CFR Part 1610	Determine flammability or flame spread	Class 1	Class 1

All results of testing met ASTM F2100 acceptance criteria.

X. Summary of Clinical Testing

No clinical study is included in this submission

XI. CONCLUSIONS

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