October 7, 2020

Andon Health Co., Ltd.
Liu Yi
President
No. 3 Jin Ping Street, Ya An Road, Nankai District
Tianjin, Tianjin 300190
China

Re: K201380
Trade/Device Name: Livocare Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 8, 2020
Received: July 10, 2020

Dear Liu Yi:

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 Elizabeth Claverie
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)*
K201380

Device Name

Livocare Surgical Mask

Indications for Use *(Describe)*

The Livocare Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The surgical mask is intended for use in infection control practices to reduce potential exposure to blood and body fluids. The surgical 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

(In accordance with 21 CFR 807.92)

1.0 Submitter's information

Name: Andon Health Co., Ltd.
Address: No 3, Jinping Street, Ya An Road, Nankai District, Tianjin P. R. China
Phone number: 86-22-87611660
Fax number: 86-22-87612379
Contact: Liu Yi
Date of preparation: October 5, 2020

2.0 Device information

Trade name: Livocare Surgical Mask
Common name: Surgical mask
Regulation name: Surgical Apparel

3.0 Classification

Product code: FXX
Regulation number: 21 CFR §878.4040
Classification: Class Ⅱ
Panel: General Hospital

4.0 Predicate device information

Manufacturer: WUHAN DYMEX HEALTHCARE CO., LTD
Device: SURGICAL FACE MASK
510(k) number: K182515

5.0 Intended use

The Livocare Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The surgical mask is intended for use in infection control

practices to reduce potential exposure to blood and body fluids. The surgical mask is a single use, disposable device, provided non-sterile.

6.0 Device description

The Livocare Surgical Mask is a single use, three-layer, flat-folded mask with ear loops and nose piece. The Surgical Mask is 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 surgical mask. The nose piece in the layers of surgical mask is to allow the user to fit the mask around their nose, which is made of malleable polyethylene wire. The mask is a single use, disposable device, provided non-sterile.

This device is not made from Natural Rubber Latex.

7.0 Comparison of technological characteristics with predicate device

Item	Subject Device	Predicate Device (K182515)	Comparison
Manufacturer	Andon Health Co., Ltd	WUHAN DYMEX HEALTHCARE CO., LTD	-
510K number	K201380	K182515	-
Product name	Livocare surgical	Surgical face mask	-
Classification	Class II, FXX, 21 CFR 878.4040	Class II, FXX, 21 CFR 878.4040	Same
Indications for Use	The Livocare Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The surgical mask is intended for use in infection control practices to reduce potential exposure to blood and body fluids. The surgical mask 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(s), provided non-sterile.	Same

Model		Ear loops, flat pleated, 3 layers	Ear loops, flat pleated, 3 layers	Same
Materials	Outer layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose piece	Malleable polyethylene wire	Malleable polyethylene wire	Same
	Ear loops	Spandex and Nylon	Spandex	Similar
Color		Outer layer: Blue Middle and inner layers: White	Yellow	Different
Dimension (Width)		9.5 ± 1.0 cm	9.5 ± 0.2 cm	Same
Dimension (Length)		17.0 ± 1.0 cm	17.5 ± 0.2 cm	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

8.0 Non-clinical testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications as the predicate device. The test results demonstrate that the proposed device conforms to the recognized standards ASTM F2100-19, ASTM F1862, ASTM F2101, and ISO 10993 in addition to the requirements stated in *the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission* issued on March 5, 2004.

***Performance testing*:**

Item	Acceptance criteria (Level 2)	Proposed device	Predicate device (K182515)	Results
Fluid Resistance ASTM F1862	29 out of 32 pass at 120 mmHg	32 out of 32 passed at 120 mmHg	32 out of 32 passed at 120 mmHg	Pass
Particulate Filtration Efficiency ASTM F2299	≥98%	> 98%	99.7%	Pass
Bacterial Filtration Efficiency ASTM F2101	≥98%	> 99%	99.9%	Pass
Differential Pressure (Delta P) MIL-M-36954C	< 6.0mmH_2O/cm^2	< 5.0mmH_2O/cm^2	4.0mmH_2O/cm^2	Pass
Flammability 16 CFR 1610	Class 1	Class 1	Class 1	Pass

Biocompatibility testing:

Item	Proposed device	Result
Cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	Pass
Irritation	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	Pass
Sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	Pass

9.0 Clinical Test

No clinical study is included in this submission.

10.0 Comparison to the predicate device and conclusion

The subject and predicate devices have the same intended use, design and mask materials. The difference between the two devices is their color, which should not raise different questions of safety and effectiveness.

The conclusion drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate K182515 Surgical Face Mask from Wuhan Dymex Healthcare.