February 12, 2021

Amphastar Nanjing Pharmaceuticals, Inc.
Bob Bao
Quality Management Representative
No.5 Xinghe Road, Nanjing Economic and Technological
Development Zone
Nanjing, Jiangsu 210038
China

Re: K201545
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 1, 2020
Received: June 9, 2020

Dear Bob Bao:

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 and Part 809); 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201545

Device Name
Surgical Face Mask

Indications for Use *(Describe)*
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.

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

K201545

Date Summary Prepared: 2021-01-06

A. Applicant:

Amphastar Nanjing Pharmaceuticals, Inc.
Address: No. 5 Xinghe Road, Nanjing Economic and Technological Development Zone. Jiangsu, China 210038
Contact Person: Bob Bao, Representative of Quality System Management
Tel: 86-025-85807880-211
Fax: 86-025-85802275
E-mail: bobb@amphastar.cn
FDA Registration Number: 3009805706

B. Device:

Trade Name: Surgical Face Mask
Common Name: Surgical Face Mask
Model(s): Ear Loop

Regulatory Information
Classification Name: Surgical Face Mask
Classification: Class II.
Product code: FXX
Regulation Number: 878.4040
Review Panel: Surgical Apparel

C. Predicate device:

K182515
Surgical Face Mask
Wuhan Dymex Healthcare Co.,Ltd

D. Indications for Use:

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.

E. Device Description:

The Surgical Face Masks are single use, three-layer, flat-folded masks with ear loops and nose piece. The Surgical Face Masks are 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 facemask. The elastic ear loops are not made with natural rubber latex. The nose piece in the layers of facemask is to allow the user to fit the facemask around their nose, which is made of plastic wire. The surgical face masks are sold non-sterile and are intended to be single use, disposable devices.

F. Summary of Technological Characteristic

Table 1 General Comparison

Item(s)	**Proposed Device (K201545)** **Surgical Face Mask** **ASTM Level 2**	**Predicate (K182515)** **Surgical Face Mask** **ASTM Level 2**	**Comparison**
Manufacturer	Amphastar Nanjing Pharmaceuticals, Inc.	Wuhan Dymex Healthcare Co., Ltd	-
510K number	K201545	K182515	-
Model Name	Surgical Face Mask	Surgical Face Mask	Same
Classification	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same

Item(s)		Proposed Device (K201545) Surgical Face Mask ASTM Level 2	Predicate (K182515) Surgical Face Mask ASTM Level 2	Comparison
Intended Use		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.	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
Material	**Outer Facing Layer**	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle Layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner Facing Layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose Piece	Plastic wire	Malleable aluminum wire	Different
	Ear Loops	Spandex	Spandex	Same
Color		Blue	Yellow	Different
Dimension (Width)		9.5cm (±5%)	9.5cm±0.2 cm	Same
Dimension (Length)		17.5cm (±5%)	17.5cm±0.2 cm	Same
Dimension (Nose Piece)		9 cm ± 5%	9 cm ± 5%	Same
Dimension (Ear Loops)		15 cm ± 5%	15 cm ± 5%	Same
OTC use		YES	YES	Same
Sterility		Non-Sterile	Non-Sterile	Same

Item(s)	Proposed Device (K201545) Surgical Face Mask ASTM Level 2	Predicate (K182515) Surgical Face Mask ASTM Level 2	Comparison
Use	Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100 Level	Level 2	Level 2	Same
Biocompatibility			
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic	Same	Same
Skin Sensitization Test	Under the conditions of the study , the device is non-sensitizing	same	Same
Skin Irritation Test	Under the conditions of the study the device is non-irritating	Same	Same

G. Non-clinical Test performed on the proposed device

The proposed devices were 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.

Table 2 Performance Testing

Item(s)	Proposed Device (k201545)	Predicate (k182515)	Acceptance Criteria	Result
Resistance to penetration by synthetic blood ASTM F1862	32 out of 32 passed in 120 mm Hg	32 out of 32 passed in 120 mm Hg	29 out of 32 pass in 120 mm Hg	Pass
Sub-micron particulate filtration efficiency at 0.1 micron ASTM F2299	>98%	99.7%	⩾98%	Pass
Bacterial filtration efficiency ASTM F2101-19	>98%	99.9%	⩾98	Pass
Differential pressure EN 14683: 2019	≤ 3.0 mm H_2O/cm_2	4.0 mm H_2O/cm_2	< 6.0	Pass

Item(s)	Proposed Device (K201545)	Acceptance Criteria	Result
Flame spread **16 CFR 1610**	Class 1 Non Flammable	Class 1	Pass

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

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 predicated K182515, Wuhan Dymex Medical Products Surgical Face Mask.