August 26, 2020

BYD Precision Manufacturer Co.Ltd.
℅ Annie Zhang
Regulatory Affairs
Nova Clinical Solutions, Inc.
6792 Solterra Vista Pkwy
San Diego, California 92130

Re: K200923
Trade/Device Name: Single-use Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 6, 2020
Received: April 7, 2020

Dear Annie Zhang:

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)*
K200923

Device Name
Single-Use Surgical Masks (Model:FE2311)

Indications for Use *(Describe)*
The Single-use Surgical Masks (Model:FE2311) 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

August 26, 2020

A. 510(k) Submitter:

BYD Precision Manufacturer Co.Ltd.
No.3001 Baohe Road, Baolong Industrial Area, Longgang
Shenzhen, Guangdong, 518116, CHINA

B. Submitter Contact:

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Designated Submission Correspondent:
Annie Zhang
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annie.zhang@huanuoclinical.com

C. Device

Trade Name:
Single-use Surgical Mask
Model: **FE2311**

Device Classification:
Class II, Surgical Face Mask (21 CFR 878.4040)

Product Code:
FXX

D. Predicate:
K153496
Disposable Surgical Face Mask
Xiantao Rayxin Medical Products Co.,Ltd.

E. Intended Use/Indications for Use:

The Single-use Surgical Masks (Model: **FE2311**) 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.

F. Device Description:

The proposed device(s) are Blue color, and Flat Pleated type mask, utilizing Ear Loops way for wearing, and they all has Nose Piece design for fitting the facemask around the nose.

The proposed device(s) 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 model of proposed device, ear loops, is 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 contained in the proposed device(s) is in the layers of facemask to allow the user to fit the facemask around their nose, which is made of metal core plastic. The proposed device(s) are sold non-sterile and are intended to be single use, disposable device.

G. Technological Characteristics:

The Single-use Surgical Mask is compared with the predicate device Disposable Surgical Face Mask (K153496) . The product characteristics are shown below in the Comparison Tables:

Table 1: General Comparison Table

Item(s)		Subject Device	Predicate Device (K153496)	Comparison
Intended Use/Indications for Use		The Single-use Surgical Masks (Model:**FE2311**) 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 Disposable 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
Type		Ear loop, Flat Pleated, 3 layers	Ear Loops and Tie-On, Flat Pleated, 3 layers	Difference
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	Metal Core Plastic	Malleable aluminum wire	Difference
	Ear Loops	Polyester	Polyester	Same
Color		Blue	Blue	Same
Dimension (Width)		17.5 cm +/- 0.4 cm	17.5 cm +/- 1 cm	Difference
Dimension (Length)		9.5 cm +/- 0.4 cm	9.5 cm +/- 1 cm	Same
OTC Use		Yes	Yes	Same
Single Use		Yes	Yes	Same
Sterile		No	No	Same
ASTM F2100 Level		Level 3	Level 2	Difference

H. Non-Clinical Test

Non clinical tests were conducted 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 05, 2004.

Standards:

- ASTM F2100-19, Standard Specification For Performance Of Materials Used In Medical Face Masks.
- ASTM F1862-13, Standard Test Method For Resistance Of Medical Face Masks To Penetration By Synthetic Blood (Horizontal Projection Of Fixed Volume At A Known Velocity).
- ASTM F2299-03, Stand Test Method For Determining The Initial Efficiency Of Materials Used In Medical Face Masks To Penetration By Particulates Using Latex Spheres.
- 16 CFR 1610, Standard For The Flammability Of Clothing Textiles.
- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices – Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation Of Medical Devices – Part 10: Tests For Irritation And Skin Sensitization.

Table 2: Performance Characteristic Comparison Table

Item(s)	Subject Device	Predicate Device (K153496)	Comparison
Fluid Resistance Performance	32 out of 32 Pass at 160 mmHg (ASTM F1862)	32 out of 32 pass at 120 mmHg (ASTM F1862)	Difference
Particulate Filtration Efficiency	Pass at 99.67% (ASTM F2299)	98.46% (ASTM F2299)	Difference

Bacterial Filtration Efficiency	Pass at 99.95% (ASTM F2100)	98.7% (ASTM F2101)	Difference
Differential Pressure	5.62 mmH_20/cm^2 (ASTM F2100)	4.2 mmH_20/cm^2 (MIL-M-36954C)	Difference
Flammability	Class 1 (16 CFR 1610)	Class 1 (16 CFR 1610)	Same

Table 3: Biocompatibility Comparison Table

Item(s)	Subject Device	Predicate Device (K153496)	Comparison
Cytotoxicity	Under the conditions of the study, not cytotoxicity effect	Comply with ISO 10993-5	Same
Irritation	Under the conditions of the study, not an irritant	Comply with ISO 10993-10	Same
Sensitization	Under the conditions of the study, not a sensitizer		

I. Clinical Test

No clinical study is included in this submission.

J. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device, the Disposable Surgical FaceMask (k153496) manufactured by Xiantao Rayxin Medical Products Co.,Ltd.