December 2, 2021

Puravita M, LLC
% Rhonda Alexander
Sr. Consultant, Regulatory Strategy
IUVO Consulting, LLC
P.O. Box 56436
Virginia Beach, Virginia 23456

Re: K212740
Trade/Device Name: Puravita Medical Fold Flat Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 25, 2021
Received: August 30, 2021

Dear Rhonda Alexander:

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 Clarence W. Murray, III, Ph.D.
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)*

K212740

Device Name
Puravita Medical Fold Flat Surgical Mask

Indications for Use *(Describe)*
The Puravita Medical Fold Flat Surgical Mask is intended to be worn to protect both patients and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. The Puravita Medical Fold Flat Surgical Mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single-use, disposable device that is 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.

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510(k) Summary

K212740

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

Date of Summary: November 24, 2021

Contact Information

Submitter:
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Device Information

Trade Name:	PuraVita Medical Fold Flat Surgical Mask
Common Name:	Surgical Face Mask
Classification Name:	Mask, Surgical
Classification:	Class II per 21 CFR 878.4040
Review Panel:	General Hospital
Product Code:	FXX

Predicate Device:

Manufacturer:	Guangdong Kingfa Sci. & Tech. Co., Ltd,
Product:	Medical Protective Mask
510(k) Number:	K202107

Intended Use Statement:
The PuraVita Medical Fold Flat Surgical Mask is intended to be worn to protect both patients and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. The PuraVita Medical Fold Flat Surgical Mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single-use, disposable device that is provided non-sterile.

Device Description:

The PuraVita Medical Fold Flat Surgical Mask is a 4-layer, two panel fold-flat surgical mask. It is comprised of polypropylene spunbond inner and outer layers and two inner polypropylene meltblown filter layers. The mask is white with an extended chamber. The dimensions of each mask are length 16.3cm ± 0.5cm and width 10.6cm ± 0.5cm. The mask has nylon/spandex earloops (length 19.5cm ± 1cm) and a malleable, metal-core nosepiece (0.4cm x 8.2cm x 0.1cm) to provide a functional fit over the nose and mouth of the user. It is a non-sterile, single use, disposable device. This device is not made with natural rubber latex.

Comparison to predicate device:

Device	**Predicate Device: K202107 Guangdong Kingfa Sci. & Tech. Co., LTD, Medical Face Mask, Model KF-A F02(N)**	**Subject Device: K212740 PuraVita Medical Fold Flat Surgical Mask**	**Comparison**
Intended Use/Indications for Use	The Medical Protective Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The Medical Protective Mask is 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 PuraVita Medical Fold Flat Surgical Mask is intended to be worn to protect both patients and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. The PuraVita Medical Fold Flat Surgical Mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single-use, disposable device that is provided non-sterile.	Similar
Materials			
Outer Layer	Polypropylene spunbond	Polypropylene spunbond	Same
Middle Filter Layer #1	Polypropylene Meltblown	Polypropylene Meltblown	Same
Middle Filter Layer #2	Non-woven Polypropylene	Polypropylene Meltblown	Different. Although the 2nd filter layer of the subject device is different than the predicate device, the device met all standards when tested.
Inner Layer	Polypropylene spunbond	Polypropylene spunbond	Same
Ear Loops	Spandex and Polyester	Spandex and Nylon	Different. Although the material used in the subject device is slightly different than the predicate device, it passed all biocompatibility test requirements.
Nose Piece	Iron core polypropylene strip	Dual Iron core polypropylene strip	Similar
Latex	Not made with natural rubber latex	Not made with natural rubber latex	Same
Description			
Color	White	White	Same
Style	Extended chamber flat-folded	Fold Flat	Similar
Single Use	Yes	Yes	Same
Sterility	Non-Sterile	Non-sterile	Same
Length	16.2cm ± 0.5cm	16.3cm ± 0.5cm	Different. Although the specifications and dimensions of the subject device are slightly different than

			the predicate device, the differences are minimal.
Width	10.2cm ± 0.5cm	10.6cm ± 0.5cm	Different. Although the specifications and dimensions of the subject device are slightly different than the predicate device, the differences are minimal.
Performance Testing			
ASTM Performance Level	ASTM Level 2	ASTM Level 3	Different. Although the performance of the subject device differs from that of the predicate device, the subject device performs at least as well as the predicate.
Fluid/Blood Penetration F1862	Pass at 120 mmHg	Pass at 160mmHg	Different, however the subject device filters as well as the predicate device.
Particulate Filtration F2299	99.1%, filtration efficiency	>99.4% filtration efficiency	Different; however, the subject and predicate devices both pass the test at ≥98% filtration efficiency.
Bacterial Filtration F2101	99.9%	>99.9%	Same
Diff. Pressure (Delta-P) MIL-M-36954C	On average of 5.04 mmH_2O/cm^2	On average 5.3 mmH_2O/cm^2	Different, both the subject device and predicate device pass the test with a differential pressure $<6.0mmH_2O/cm^2$.
Flammability 16 CFR 1610	Class 1	Class 1	Same
Biocompatibility Testing			
Cytotoxicity	Non-Cytotoxic	Non-Cytotoxic	Same
Skin Irritation	Non-Irritating	Non-Irritating	Same
Skin Sensitization	Non-Sensitizing	Non-Sensitizing	same

- Middle Layer #2 – the subject device is constructed using meltblown polypropylene, while the predicate device is constructed with non-woven polypropylene. The mask meets the same testing requirements as the subject device.
- Ear Loops – the subject device's ear loops are constructed with spandex and nylon, while the predicate device's loops are made with spandex and polyester. Despite this difference in material composition, the ear loops of the subject device meet all biocompatibility requirements; the difference does not negatively affect performance of the device.
- The dimensions (length and width) of the subject and predicate devices differ by 0.1cm. This is within normal limits of variation (± 0.5cm).

- Performance Testing (Fluid/Synthetic Blood Penetration ASTM F1862) – the subject and predicate devices differ in performance of fluid penetration testing. The subject device resists penetration by blood at the same level as the predicate device.
- Performance Testing (Particulate Filtration Efficiency ASTM F2299) – the subject performed differently from the predicate device; however, subject and predicate devices both passed the test at ≥ 98% filtration efficiency, meeting the requirements for levels 2 and 3.
- Performance Testing (Differential Pressure EN 14683:2019) – While the average differential pressures differ between the subject and predicate devices, both have average differential pressure values that pass the test at <6.0mmH_2O/cm^2.
- There were no differences between the biocompatibility of the subject and predicate devices.

Summary of Bench Performance Testing

Test	Device Description/ Sample Size	Test Method/Applicable Standards	Acceptance Criteria	Unexpected Results/ Significant Deviations	Results
Bacterial Filtration Efficiency ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus FDA Recognition Number: 6-427 **Objective of the test:** Evaluate the bacteria filtration efficiency (BFE) of face masks samples, using a biological aerosol of Staphylococcus aureus.	**Test articles used in the test** 32 samples of PuraVita Medical Fold Flat Surgical Masks from 3 non-sequential lots (total of 96 samples) were tested; final finished devices	**Test methods and procedures (including any specific test conditions)** ASTM F2101-19 method was followed under standard conditions with no deviations	**Study endpoint, i.e., the specific parameter measured** Bacterial filtration efficiency **Pre-defined acceptance or pass/fail criteria.** Level 2 Barrier: ≥ 98% filtration efficiency Level 3 Barrier: ≥ 98% filtration efficiency	None	All samples tested at least 98% filtration efficiency. All 96 samples meet the "pass" criteria of the test for levels 2 and 3. Comparative testing of the predicate device was not performed, since information regarding its performance can be obtained from FDA's public database. The predicate device passed at 99.9% filtration efficiency. When compared to the information in the public summary, the subject device and predicate device are Similar.
Differential Pressure (Delta-P)	**Test articles used in the test**	**Test methods and procedures (including any**	**Study endpoint, i.e., the specific parameter measured**	None	All 96 samples measured an average differential pressure <6.0 mmH_2O/cm^2.

EN 14683:2019 + AC 2019 (E) Annex C: Medical Face Masks - Requirements and Test Methods; Method for determination of breathability **Objective of the Test:** Determine the breathability of masks by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate of 8 L/min.	32 samples of PuraVita Medical Fold Flat Surgical Masks from 3 non-sequential lots (total of 96 samples) were tested; final finished devices	**specific test conditions)** EN 14683:2019 + AC 2019 (E) Annex C method was followed under standard conditions with no deviations	Pressure in mmH_2O/cm^2 **Pre-defined acceptance or pass/fail criteria.** Passing differential pressure must be $< 6.0mmH_2O/cm^2$.		(The average pressure was $5.3mmH_2O/cm^2$.) Comparative testing of the predicate device was not performed, since information regarding its performance can be obtained from FDA's public database. The predicate device had an average differential pressure of $5.04mmH_2O/cm^2$. When compared to the information in the public summary, the subject device and predicate device were found to be Similar.
Sub-Micron Particulate Filtration Efficiency at 0.1um of Polystyrene Latex Spheres ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks (Parent Standard of ASTM F2299/F2299M-03 (Reapproved 2017) – Test Method for Determining the Initial Efficiency of Materials used in Medical Face Masks to Penetration by Particulates Using Latex Spheres) **Objective of Test:** Determine the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres	**Test articles used in the test** 32 samples of PuraVita Medical Fold Flat Surgical Masks from 3 non-sequential lots (total of 96 samples) were tested; final finished devices	**Test methods and procedures (including any specific test conditions)** ASTM F2299/F2299M-03 (reapproved 2017) method was followed under standard conditions with no deviations	**Study endpoint, i.e., the specific parameter measured** Sub-micron particulate filtration at 0.1 micron **Pre-defined acceptance or pass/fail criteria.** Level 1 Barrier: ≥ 95% filtration efficiency Level 2 Barrier: ≥ 98% filtration efficiency Level 3 Barrier: ≥ 98% filtration efficiency	None	All samples filtered at a level ≥ 98% filtration efficiency All samples meet the standard's requirements for Level 2 filtration and met the same criteria as the predicate. Comparative testing of the predicate device was not performed, since information regarding its performance can be obtained from FDA's public database. The predicate device's particulate filtration efficiency was 99.1%. When compared to the information in the public summary, the subject device and predicate device were found to be Similar, as they meet the requirements of the same level of filtration efficiency.

Flammability 16 CFR 1610 Standard for the flammability of clothing textiles. 73 FR 62187, Oct. 20, 2008 **Objective of the Test:** Evaluate the flammability of face mask samples, prohibiting the use of any dangerous flammable materials	**Test articles used in the test** 32 samples of PuraVita Medical Fold Flat Surgical Masks from 3 non-sequential lots (total of 96 samples) were tested; final finished devices	**Test methods and procedures (including any specific test conditions)** The method described in 16 CFR 1610 was followed under standard conditions with no deviations	**Study endpoint, i.e., the specific parameter measured** Textile's burn time (the time elapsed from ignition until the stop thread is severed as measured by the timing mechanism of the test apparatus.) **Pre-defined acceptance or pass/fail criteria.** Class I criteria: The sample does not ignite (DNI) or ignites but extinguishes (IBE). Or burn time, as defined by the standard is ≥ 3.5 seconds	None	All samples either did not ignite (DNI) or ignited but extinguished (IBE). All samples met the requirements for Class I Flammability. Comparative testing of the predicate device was not performed, since information regarding its performance can be obtained from FDA's public database. The predicate device met the requirements for Class I flammability. When compared to the information in the public summary, the subject device and predicate device were found to be Similar.
Resistance to Penetration by Synthetic Blood 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) FDA Recognition Number: 6-406 **Objective of the Test:** Measure the resistance of medical face masks samples to penetration by synthetic blood.	**Test articles used in the test** 32 samples of PuraVita Medical Fold Flat Surgical Masks from 3 non-sequential lots (total of 96 samples) were tested; final finished devices	**Test methods and procedures (including any specific test conditions)** The method described in F1862/F1862M-17 was followed under standard conditions with no deviations	**Study endpoint, i.e., the specific parameter measured** Visual detection of synthetic blood penetration. **Pre-defined acceptance or pass/fail criteria.** Pass criteria: No visual blood penetration	None	None of the tested samples showed penetration of synthetic blood up to 160mmHg. All samples passed the requirements of the test and performed as well as the predicate. Comparative testing of the predicate device was not performed, since information regarding its blood penetration performance can be obtained from FDA's public database. The predicate device resisted penetration at 120mmHg. When compared to the information in the public summary, the subject device and predicate device were found to be Similar.

Comparison of Performance Testing

When compared to FDA's public information regarding the predicate's performance, the subject device was found to perform similarly to or exactly the same as the predicate.

Test	Predicate	Subject	Comparison
Bacterial Filtration Efficiency	> 99.1% Filtration Efficiency Pass	≥ 98% Filtration Efficiency Pass	Similar, both the subject device and predicate device passed the test at the same level (≥98%).
Differential Pressure (Delta-P)	< 6.0 mmH_2O/cm^2 Pass	< 6.0 mmH_2O/cm^2 Pass	Same
Sub-Micron Particulate Filtration Efficiency at 0.1um of Polystyrene Latex Spheres	99.9% filtration efficiency Pass	≥ 98% filtration efficiency Pass	Similar; both the subject device and predicate device passed the test at the same level (≥98%).
Resistance to Penetration by Synthetic Blood	Fluid resistant claimed at 120mmHg Pass	Fluid resistance at 160mmHg Pass	Similar- the subject device resisted blood penetration at least as well as the predicate device.
Flammability	Class 1	Class 1	Same

Summary of Biocompatibility Testing

The nature of body contact for the subject device is Surface Device category, Skin Contact and duration of contact is limited (≤24h). The following tests were conducted on the final, finished form of the subject device to demonstrate that the subject device is biocompatible and safe for its intended use:

Test	Device Description/ Sample Size	Test Method/Applicable Standards	Acceptance Criteria	Unexpected Results/ Significant Deviations	Results
Cytotoxicity - MEM Elution Test FDA Recognition Number: 2-245 **Objective of the test:** The purpose of this test was to evaluate the cytotoxic potential of extracts of polymeric materials or any other materials intended to be implanted in the human body or that may come into contact with bodily fluids or injectable solutions.	**Test articles used in the test** 1 Puravita Medical Fold Flat Surgical Mask; final finished device; all components tested together as composite. (Lot No. 12142020A)	**Test methods and procedures (including any specific test conditions)** The testing standard ANSI/AAMI/ISO 10993-5:2009 was followed under standard conditions with no deviations or amendments. .	**Study endpoint, i.e., the specific parameter measured** The morphology of cells was observed at the 24 and 48 hour examination points according to the criteria stated in the ISO 10993-5 guidelines. The average score for the three test wells and controls at the 48-hour point was used to determine the cytotoxic response. **Pre-defined acceptance or pass/fail criteria.** Cell morphology graded greater than 2 is considered to have a cytotoxic effect.	None	Pass. Based on qualitative evaluation of the cells exposed to the test article extract, the test article was not considered to have a cytotoxic effect. Comparative testing of the predicate device was not performed, since information regarding its biocompatibility can be obtained from FDA's public database. When compared to the information in the public summary, the subject device and predicate device were both found to be non-cytotoxic.
Sensitization - Maximization Test for Delayed-Type Hypersensitivity in Hartley Guinea Pigs (ISO 10993-10:2010) FDA Recognition Number: 2-174 **Objective of the test:** The purpose of this test was to determine to what extent the test article has the potential to act as a contact sensitizer in guinea pigs.	**Test articles used in the test** 6 Puravita Medical Fold Flat Surgical Masks; final finished devices; all components tested together as composite. (Lot no. 12142020A)	**Test methods and procedures (including any specific test conditions)** The study was performed according to ISO 10993-10 guidelines, with no deviations or amendments.	**Study endpoint, i.e., the specific parameter measured** In the final analysis of data, consideration was given to the overall patterns, intensity, duration, and the nature of reactions of the test as compared with the control. **Pre-defined acceptance or pass/fail criteria.** Any skin reaction scores received by the test group, which were greater than the scores received by the negative control group, were considered to represent sensitization.	None	Pass. No sensitization reactions or patterns were noted in animals exposed to test article extracted in either saline or cottonseed oil. The test animals did not receive scores higher than those of the negative control animals. Comparative testing of the predicate device was not performed, since information regarding its biocompatibility can be obtained from FDA's public database. When compared to the information in the public summary, the subject device and predicate device were both found to be non-sensitizing.

Intracutaneous (Intradermal) Reactivity Test ISO 10993-10:2010 Intracutaneous (Intradermal) Reactivity Test in New Zealand White Rabbits FDA Recognition Number: 2-174 **Objective of the test:** The purpose of this test was to evaluate local responses to extracts of the test article following intracutaneous injections into rabbits.	**Test articles used in the test** 2 Puravita Medical Fold Flat Surgical Masks final, finished devices; all components tested together as composite. (Lot No 12142020A)	**Test methods and procedures (including any specific test conditions)** The study was performed according to ISO 10993-10 guidelines, with no deviations or amendments.	**Study endpoint, i.e., the specific parameter measured** Injection sites were observed for erythema, eschar formation, edema, and necrosis, and scored at 24 ± 2 hours, 48 ± 2 hours, and 72 ± 2 hours. The average scores for the test sites were calculated and compared to the average scores for the control sites. **Pre-defined acceptance or pass/fail criteria.** According to ISO 10993-10, the requirements of the test are met if the difference between the test article extract average score and the control average score is 1.0 or less and the test does not fail at any observation period.		Pass. Based on erythema and edema scores, the test article extracted in saline or cottonseed oil did not elicit biologically significant irritation reactions when compared to the control after being injected intracutaneously. Both the subject and predicate devices were found to be non-irritating. Comparative testing of the predicate device was not performed, since information regarding its biocompatibility can be obtained from FDA's public database. When compared to the information in the public summary, the subject device and predicate device were both found to be non-irritating.

Comparison of Biocompatibility Results Between the Subject & Predicate Devices

	Predicate Device (K202107)	**Subject Device PuraVita Medical Fold Flat Surgical Mask**	**Comparison**
Cytotoxicity	Not Cytotoxic	Not Cytotoxic	Same
Sensitization	No Sensitization Occurred	No Sensitization Occurred	Same
Intracutaneous (Intradermal) Reactivity Test	No Irritation Reaction Observed	No Irritation Reaction Observed	Same

Animal & Clinical Performance Testing

No animal or clinical tests were performed on the subject device for this submission.

IVD Statement

The subject device is not an *in vitro* diagnostic device.

Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K212740, the PuraVita Medical Fold Flat Surgical Mask, is as safe, as effective, and performs as well as or better than the legally marketed predicate device K202107.