September 17, 2025

Vitacore Industries Inc.
Yuxuan Fan
R&D Project Manager
1615 Kebet Way
Port Coquitlam, BC V3C 5W9
Canada

Re: K251902
Trade/Device Name: Vitaform Procedural Mask - Blue (Vitaform Blue); Vitaform Procedural Mask with Shield (Vitaform-FS)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 20, 2025
Received: June 20, 2025

Dear Yuxuan Fan:

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 (the 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 available 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not

required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

ALLAN GUAN -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251902

Device Name
Vitaform Procedural Mask - Blue (Vitaform Blue); Vitaform Procedural Mask with Shield (Vitaform-FS)

Indications for Use *(Describe)*
Vitaform Procedural Masks are intended to be worn to protect both the patient and the healthcare worker from transfer of microorganisms, body fluids, and particulate material. They are single-use and intended for use in infection control practices to reduce potential exposure to blood and body fluids.

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

K251902

Submitter

Sponsor and Correspondent Information

Submitted By:	Vitacore Industries Inc.
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Date Prepared

September 17th, 2025

Device

Device Information

Device Name:	Vitaform Procedural Mask - Blue (Vitaform Blue); Vitaform Procedural Mask with Shield (Vitaform-FS)
Device Classification Name:	Surgical Apparel
Product Code:	FXX
Regulation Number:	21 CFR 878.4040
Classifications:	Class II, 21 CFR 878.4040 - Surgical Apparel

Predicate device

Primary Predicate: Magnum Surgical Mask, K220670
Additional Predicate: 3M™ High Fluid-Resistant Procedure Mask with Face Shield (Model# 1840FS), K191355

Device Description

Vitaform Procedural Mask (henceforth referred to as "Vitaform")

The Vitaform Procedural Mask is a single-use, three-layered, fish-shaped surgical mask with ear loops and an aluminum nose piece. The inner and outer layers are made of spunbond polypropylene, and the middle filter layer consists of meltblown polypropylene. The ear loops are made of PET and Spandex material, and worn around the ears to keep the mask close to the face. The nose piece is a flexible aluminum strip that is fitted over the nose so that the mask conforms better to the user's face.

The Vitaform Procedural Mask is provided in the color blue. It is non-sterile and intended to be a single-use, disposable medical device.

Vitaform Procedural Mask with Shield (henceforth referred to as "Vitaform-FS")

The Vitaform Procedural Mask with Shield is a single-use, fish-shaped surgical mask with ear loops and an aluminum nose piece. The inner and outer layers are made of spunbond polypropylene, and

the middle filter layer consists of meltblown polypropylene. The insertion layer that provides structural support is made of thermal-bonded polypropylene. The ear loops are made of PET and Spandex material, and is worn around the ears to keep the mask close to the face. The nose piece is a flexible aluminum strip that is fitted over the nose so that the mask conforms better to the user's face. The mask also contains a face shield (FS) made from a polyethylene terephthalate film, and an anti-reflective flap. The face shield is welded to the upper half of the mask to cover the upper part of the face.

The Vitaform Procedural Mask with Shield is provided in the color blue. It is non-sterile and intended to be a single-use, disposable medical device.

Indications for Use

Vitaform Procedural Masks are intended to be worn to protect both the patient and the healthcare worker from transfer of microorganisms, body fluids, and particulate material. They are single-use and intended for use in infection control practices to reduce potential exposure to blood and body fluids.

Comparison of the Technological Characteristics with the Predicates

The table below compares the construction, technology, design, claims, and intended use of the proposed (Vitaform and Vitaform-FS) and predicate devices.

Table 1 - Comparison of Proposed (Vitaform and Vitaform-FS) and Predicate Devices

Device	**Proposed Devices Vitaform, Vitaform-FS**	**Primary Predicate**	**Additional Predicate**	**Results**
510K #	K251902	K220670	K191355	Different
Product Code	FXX	FXX	FXX	Same
Product Owner	Vitacore Industries Inc.	Magnum Health and Safety Pvt Ltd	3M Health Care	Different
Intended Use	Vitaform Procedural Masks are intended to be worn to protect both the patient and the healthcare worker from transfer of microorganisms, body fluids, and particulate material. They are single-use and intended for use in infection control practices to reduce potential exposure to blood and body fluids.	When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids, and particulate material. The face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This device is disposable,	3M™ High Fluid-Resistant Procedure Mask is 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 potential exposure to blood and body fluids. This is a single use, disposable device,	Similar

		non-sterile and for single use only.	provided non-sterile.	
Regulation Number	Class II, 21 CFR 878.4040	Class II, 21 CFR 878.4040	Class II, 21 CFR 878.4040	Same
Mask Style	Vitaform: Fish-shaped mask with earloop Vitaform-FS: Fish-shaped mask with earloop and visor attachment	Flat - Pleated	Flat - Pleated	Different
Multiple Layers	Yes	Yes	Yes	Same
Mask Color(s)	Vitaform: Blue Vitaform-FS: Blue	Blue	Green (Outer)	Different
Materials and Specifications				
Outer layer	Vitaform Blue, Vitaform-FS: Blue spunbond polypropylene	Spunbond polypropylene	Polypropylene Spunbond	Same
Insertion	**Vitaform-FS only:** Polypropylene Thermal-bonded	N/A	Polypropylene Spunbond	Different
Filter layer	Polypropylene Meltblown	Meltblown filter media	Polypropylene Meltblown	Similar
Inner layer	Polypropylene Spunbond	Spunbond polypropylene	Polypropylene Thermal-bonded	Different
Earloop	PET/Spandex	Knitted elastic	Spandex elastic cord (polyurethane core with polyethylene terephthalate / nylon cover)	Similar
Nose piece	Aluminum	PVC coated aluminum wire	Polyethylene coated steel wire	Different
Anti-Glare layer	**Vitaform-FS only:** Polypropylene Spunbond	N/A	N/A	Different
Face Shield	**Vitaform-FS only:** Polyethylene Terephthalate Film	N/A	Polyethylene Terephthalate Film	Similar
Length	215±15MM/8.5”±0.6”	172±3MM/6.9”±0.1”	175±5MM/6.9” ±0.2”	Different
Width	85±2MM/3.3”±0.08”	95±3MM/3.7”±0.1”	89±7.6MM/3.5” ±0.3”	Different
ASTM 2100 Level	Level 3	Level 2 and 3	Level 3	Similar
ASTM F2299 Particulate filtration efficiency	At least 98%	At least 98%	At least 98%	Same
ASTM F2101 Bacterial filtration	At least 98%	At least 98%	At least 98%	Same

efficiency				
Differential pressure	Less than 6.0 mmH_20/cm^2	Less than 6.0 mmH_20/cm^2	Less than 6.0 mmH_20/cm^2	Same
ASTM F1862 Fluid resistance	Pass at 160 mmHg	Level 2: Pass at 120 mmHg Level 3: Pass at 160 mmHg	Pass at 160 mmHg	Similar
16 CFR 1610 Flammability	Class I	Class I	Class I	Same
Sterility	Non-sterile	Non-sterile	Non-sterile	Same
Prescription vs. OTC	OTC	OTC	OTC	Same
Use	Single use, disposable	Single use, disposable	Single use, disposable	Same
Biocompatibility Cytotoxicity	Under the conditions of the study, non-cytotoxic	Under the conditions of the study, non-cytotoxic	Under the conditions of the study, non-cytotoxic	Same
Biocompatibility Irritation	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Same
Biocompatibility Sensitization	Under the conditions of the study, non-sensitizing	Under the conditions of the study, non-sensitizing	Under the conditions of the study, non-sensitizing	Same
Shelf Life	Predetermined Change Control Plan for future three year shelf life	Not specified	Not specified	Different

Test results for all the subject devices were similar to results for the ASTM F2100 Level 3 predicates, and exceed the test results for the ASTM F2100 Level 2 variant of the primary predicate. While the subject device is a fish-shape design and the predicates are flat pleated, the devices meet the same performance criteria.

Summary of Non-Clinical Testing

Non-clinical tests were performed on the Vitaform and Vitaform-FS to verify that the proposed device met all design specifications as the Magnum surgical mask (K220670). The test results showed that the proposed device complies with the standards and requirements set out in the Guidance for Industry and FDA staff: Surgical Masks – Premarket Notification [510K] Submission issued in 2004.

Performance Tests

- ASTM F1862, Standard Test Method for Resistance of Medical Face Masks To Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume At A Known Velocity)
- EN 14683, Medical Face Masks–Requirements and Test Methods
- ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using A Biological Aerosol of Staphylococcus Aureus
- ASTM F2299, Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particulate 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
- ISO 10993-23:2021 Biological Evaluation of Medical Devices, Part 23: Tests for Irritation

Table 2 –Performance Testing results.

Performance Tests	**Purpose**	**Criteria**	**Result**
Particulate Filtration Efficiency as per ASTM F2299	To determine the particulate filtration efficiency	Pass ≥ 98%	Pass
Bacterial Filtration Efficiency as per ASTM F2101	To determine the bacterial filtration efficiency	Pass ≥ 98%	Pass
Blood Penetration Resistance as per ASTM F1862	To determine the resistance to synthetic blood penetration	Pass at 160 mm Hg	Pass
Differential Pressure as per EN 14683 / MIL M36954C	To determine the resistance to airflow	Pass at less than 6.0 mm H_2O/cm^2	Pass
Flammability as per 16 CFR 1610	To evaluate flammability	Class I	Pass
Biocompatibility Cytotoxicity as per ISO 10993-5	To evaluate cytotoxic potential	Under the conditions of the study, non-cytotoxic	Pass
Biocompatibility Sensitization as per ISO 10993-10	To evaluate sensitization potential	Under the conditions of the study, not a sensitizer	Pass
Biocompatibility Irritation as per ISO 10993-23	To evaluate the irritation potential	Under the conditions of the study, not an irritant	Pass
Predetermined Change Control Plan for addition of three-year shelf life to label			
Verify Particulate Filtration Efficiency as per ASTM F3502 after three-years real time aging	To verify the particulate filtration efficiency after three years real time aging	Pass ≥ 85%	Not yet conducted
Verify Bacterial Filtration Efficiency as per ASTM F2101 after three-years real time aging	To verify the bacterial filtration efficiency after three years real time aging	Pass ≥ 98%	Not yet conducted
Verify Blood Penetration Resistance as per	To verify the resistance to synthetic blood penetration after three years real time aging	Pass at 160 mm Hg	Not yet conducted

ASTM F1862 after three-years real time aging			
Verify Differential Pressure as per EN 14683 / MIL M36954C	To verify the resistance to airflow after three years real time aging	Pass at less than 6.0 mm H_2O/cm^2	Not yet conducted

Summary of Clinical Testing

No clinical testing was used in support of this submission.

Conclusion

The conclusion drawn from the tests performed demonstrates that the Vitaform Procedural Mask - Blue (Vitaform Blue); Vitaform Procedural Mask with Shield (Vitaform-FS) are as safe, as effective, and perform as well as or better than the legally marketed predicate devices, Magnum Surgical Mask (K220670) and 3M™ High Fluid-Resistant Procedure Mask with Face Shield (K191355).