August 24, 2022

The GOOD Corporation
℅ Mikael Hellstrand
RA Manager
K-Bio Solutions
201 South 4th St, Suite 727
San Jose, California 95112

Re: K211771
Trade/Device Name: The GOOD High Fluid-Resistant Surgical Mask, The GOOD High Fluid-Resistant Surgical Procedure KF Mask, The GOOD Super Guard Design High Fluid-Resistant Surgical Mask, The KOEASY High Fluid-Resistant Surgical Mask, The KOEASY High Fluid-Resistant Surgical Procedure KF Mask, The KOEASY Super Guard Design High Fluid-Resistant Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 20, 2022
Received: July 25, 2022

Dear Mikael Hellstrand:

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,

Bifeng Qian, M.D., 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)*
K211771

Device Name
The GOOD High Fluid-Resistant Surgical Mask, The GOOD High Fluid-Resistant Surgical Procedure KF Mask, The GOOD Super Guard Design High Fluid-Resistant Surgical Mask, The KOEASY High Fluid-Resistant Surgical Mask, The KOEASY High Fluid-Resistant Surgical Procedure KF Mask, The KOEASY Super Guard Design High Fluid-Resistant Surgical Mask

Indications for Use *(Describe)*
The GOOD High Fluid-Resistant Surgical Mask and the KOEASY High Fluid-Resistant Surgical Mask 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 potential exposure to blood and body fluids. The face mask is single use, disposable device, provided non-sterile.
Device Name (Model Number):
The GOOD High Fluid-Resistant Surgical Mask (202001629)
The GOOD High Fluid-Resistant Surgical Procedure KF Mask (201703328)
The GOOD Super Guard Design High Fluid-Resistant Surgical Mask (201801049)
The KOEASY High Fluid-Resistant Surgical Mask (202002107)
The KOEASY High Fluid-Resistant Surgical Procedure KF Mask (201905891)
The KOEASY Super Guard Design High Fluid-Resistant Surgical Mask (201905443)

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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The assigned 510(k) Number: K211771

510(k) Summary

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

1. Submitter's Information

Sponsor Name: The GOOD Corporation
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Application Correspondent:

Contact Person: Mr. Mikael Hellstrand
Company: K-Bio Solutions
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2. Date of the summary prepared: August 24, 2022

3. Subject Device Information

Type of 510(k): Traditional
Trade Name: The GOOD High Fluid-Resistant Surgical Mask
The GOOD High Fluid-Resistant Surgical Procedure KF Mask
The GOOD Super Guard Design High Fluid-Resistant Surgical Mask
The KOEASY High Fluid-Resistant Surgical Mask
The KOEASY High Fluid-Resistant Surgical Procedure KF Mask
The KOEASY Super Guard Design High Fluid-Resistant Surgical Mask
Classification Name: Mask, Surgical
Review Panel: General Hospital
Product Code: FXX
Regulation: 21 CFR 878.4040 – Surgical Apparel
Regulatory Class: Class II

4. Predicate Device Information

Sponsor: 3M Health Care
Trade Name: 3M™ High Fluid-Resistant Surgical Mask and 3M™ High Fluid-Resistant Procedure Mask
Classification Name: Mask, Surgical
510(k) Number: K191355
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 21 CFR 878.4040
Regulation Class: Class II

5. Device Description

The subject device includes six mask models, which are listed in Table 5.0-1 below.

Table 5.0-1: Subject Device Names and Model Numbers

No.	Device Name	Model Number
1	The GOOD High Fluid-Resistant Surgical Mask	202001629
2	The GOOD High Fluid-Resistant Surgical Procedure KF Mask	201703328
3	The GOOD Super Guard Design High Fluid-Resistant Surgical Mask	201801049
4	The KOEASY High Fluid-Resistant Surgical Mask	202002107
5	The KOEASY High Fluid-Resistant Surgical Procedure KF Mask	201905891
6	The KOEASY Super Guard Design High Fluid-Resistant Surgical Mask	201905443

Each mask is composed of four-layers (outer non-woven layer, support layer, melt blown filter layer, and inner non-woven layer). Each mask contains ear loops to secure the mask over the users' mouth and face and includes a malleable nosepiece to provide a firm fit over the nose. The masks are single use, disposable devices, provided non-sterile. These devices are not made from Natural Rubber Latex.

The GOOD Surgical Mask (202001629), GOOD KF Mask (201703328), GOOD Design Mask (201801049) share the same dimensions as shown in Table 5.0-2 below. The KOEASY Surgical Mask (202002107), KOEASY KF Mask (201905891), KOEASY Design Mask (201905443) share the same dimensions as shown in Table 5.0-2 below.

Table 5.0-2: Dimensions of the GOOD Surgical Mask (202001629), GOOD KF Mask (201703328), GOOD Design Mask (201801049), KOEASY Surgical Mask (202002107), KOEASY KF Mask (201905891), and KOEASY Design Mask (201905443)

No.	Device Name	Model Number	Dimensions
1	The GOOD High Fluid-Resistant Surgical Mask	202001629	Mask Length: 210mm Mask Width: 85mm
2	The GOOD High Fluid-Resistant Surgical Procedure KF Mask	201703328	
3	The GOOD Super Guard Design High Fluid-Resistant Surgical Mask	201801049	
4	The KOEASY High Fluid-Resistant Surgical Mask	202002107	Mask Length: 220mm Mask Width: 80mm
5	The KOEASY High Fluid-Resistant Surgical Procedure KF Mask	201905891	
6	The KOEASY Super Guard Design High Fluid-Resistant Surgical Mask	201905443	

The similarities and differences between the six masks in terms of the mask components are provided in Table 5.0-3 below.

Table 5.0-3: Components of the GOOD Surgical Mask (202001629), GOOD KF Mask (201703328), GOOD Design Mask (201801049), KOEASY Surgical Mask (202002107), KOEASY KF Mask (201905891), and KOEASY Design Mask (201905443)

Component	Component Description	The GOOD High Fluid-Resistant Surgical Mask (202001629)	The GOOD High Fluid-Resistant Surgical Procedure KF Mask (201703328)	The GOOD Super Guard Design High Fluid-Resistant Surgical Mask (201801049)	The KOEASY High Fluid-Resistant Surgical Mask (202002107)	The KOEASY High Fluid-Resistant Surgical Procedure KF Mask (201905891)	The KOEASY Super Guard Design High Fluid-Resistant Surgical Mask (201905443)
Mask Components	Outer Non-Woven Layer	●	●	●	●	●	●
	Support Layer	●	●	●	●	●	●
	Melt Blown Filter Layer	●	●	●	●	●	●
	Inner Non-Woven Layer	●	●	●	●	●	●
	Ear String	●	●	●	●	●	●
	Nose Support	●	●	●	●	●	●
	Colorant (Magenta, Yellow, Cyan, Black)			●			●
Polypropylene Melt Blown Filter Density	Polypropylene Melt Blown Filter Density: 20mg/m^2	●			●		
	Polypropylene Melt Blown Filter Density: 30mg/m^2		●	●		●	●

● = Applicable component that is included in each mask model

The GOOD Design Mask (201801049) and the KOEASY Design Mask (201905443) share the same components and raw materials as shown in Table 5.0-4 below.

Table 5.0-4: Identical Components and Raw Materials for both the GOOD Design Mask (201801049) and the KOEASY Design Mask (201905443)

No.	**Component Name** for both the 201801049 and 201905443 models.	**Raw Material Chemical Name** for both the 201801049 and 201905443 models.	
1	Outer Non-Woven Fabric	Titanium dioxide	
		Polyethylene terephthalate	
		Amaranth	
		Tartrazine	
		Brilliant Blue FCF	
		Naphthol Blue Black	
		Glycerol	
2	Support Layer	Polyethylene	
		Polypropylene	
3	Melt Blown Filter Layer	Polypropylene	
		Titanium dioxide	
4	Inner Non-Woven Fabric	Polypropylene	
		Polyethylene	
5	Ear String	Nylon	Nylon 6
			Carbon Black
		Polyurethane	
6	Nose Support	Polyethylene	
		Polyethylene terephthalate	
		Iron	

The only difference between the GOOD Design Mask (201801049) and the KOEASY Design Mask (201905443) are identified below as dimensional differences:

- GOOD Design Mask (201801049): Length: 210mm, Width: 85mm
- KOEASY Design Mask (201905443): Length: 220mm, Width: 80mm

The GOOD Surgical Mask (202001629), GOOD KF Mask (201703328), KOEASY Surgical Mask (202002107), and KOEASY KF Mask (201905891) share the same components and raw materials as shown in Table 5.0-5 below.

Table 5.0-5: Identical Components and Raw Materials for the GOOD Surgical Mask (202001629), GOOD KF Mask (201703328), KOEASY Surgical Mask (202002107), and KOEASY KF Mask (201905891)

No.	**Component Name** for the 202001629, 201703328, 202002107, and 201905891 models.	**Raw Material Chemical Name** for the 202001629, 201703328, 202002107, and 201905891 models.
1	Outer Non-Woven Layer	Titanium dioxide
		Polypropylene
2	Support Layer	Polyethylene
		Polypropylene
3	Melt Blown Filter Layer	Polypropylene
		Titanium dioxide
4	Inner Non-Woven Layer	Polypropylene
		Polyethylene
5	Ear String	Nylon 6
		Polyurethane
6	Nose Support	Polyethylene
		Polyethylene terephthalate
		Iron

The only difference between the GOOD Surgical Mask (202001629), GOOD KF Mask (201703328), KOEASY Surgical Mask (202002107), and KOEASY KF Mask (201905891) are identified below as dimensional differences:

- GOOD Surgical Mask (202001629): Length: 210mm, Width: 85mm
- GOOD KF Mask (201703328): Length: 210mm, Width: 85mm
- KOEASY Surgical Mask (202002107): Length: 220mm, Width: 80mm
- KOEASY KF Mask (201905891): Length: 220mm, Width: 80mm

6. Indications for Use

The GOOD High Fluid-Resistant Surgical Mask and the KOEASY High Fluid-Resistant Surgical Mask 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 potential exposure to blood and body fluids. The face mask is single use, disposable device, provided non-sterile.

7. Comparison to Predicate Device

The differences between the subject device and predicate device do not raise new issues of safety or effectiveness.

Comparison Item	Proposed Device	Predicate Device	Note
Manufacturer	The GOOD Corporation	3M Health Care	--
510(k)	K211771	K191355	--
Trade Name	• The GOOD High Fluid-Resistant Surgical Mask • The GOOD High Fluid-Resistant Surgical Procedure KF Mask • The GOOD Super Guard Design High Fluid-Resistant Surgical Mask • The KOEASY High Fluid-Resistant Surgical Mask • The KOEASY High Fluid-Resistant Surgical Procedure KF Mask • The KOEASY Super Guard Design High Fluid-Resistant Surgical Mask	3M™ High Fluid-Resistant Surgical Mask	--
Model	• 202001629 • 201703328 • 201801049 • 202002107 • 201905891 • 201905443	• 1835 • 1835FS	--
Classification Name	Mask, Surgical	Mask, Surgical	Same
Classification	Class II	Class II	Same
Product Code	FXX	FXX	Same
Indications for Use/ Intended Use	The GOOD High Fluid-Resistant Surgical Mask and the KOEASY High Fluid-Resistant Surgical Mask are intended to be worn to protect both the patient	3M™ High Fluid-Resistant Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms,	Same

	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. The face mask is single use, disposable device, provided non-sterile.	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, provided non-sterile.	
Materials (Model 202001629, 201703328, 202002107, and 201905891)			
Outer Non-Woven Layer	Titanium dioxide Polypropylene	Polypropylene Spunbond, green	Different Note 1
Support Layer	Polyethylene Polypropylene	Polypropylene Spunbond, white	Different Note 1
Melt Blown Filter Layer	Polypropylene Titanium dioxide	Polypropylene Meltblown, white	Same
Inner Non-Woven Layer	Polypropylene Polyethylene	Polypropylene Thermalbonded, white	Different Note 1
Nose Support	Polyethylene Polyethylene terephthalate Iron	Polyethylene Coated Steel Wire	Different Note 1
Edge Wrap	Not Applicable	Polypropylene Spunbond, white or Polyethylene Terephthalate, white	Different Note 2
Ear Strings	Nylon 6 Polyurethane	Not Applicable	Different Note 1
Tie Strings	Not Applicable	Polypropylene Spunbond, white or Polyethylene Terephthalate, white	Different Note 3
Materials (Model 201801049 and 201905443)			
Outer Non-Woven Layer	Titanium dioxide Polyethylene terephthalate Amaranth Tartrazine Brilliant Blue FCF Naphthol Blue Black Glycerol	Polypropylene Spunbond, green	Different Note 1 and Note 4

Support Layer	Polyethylene		Polypropylene Spunbond, white	Different Note 1
	Polypropylene			
Melt Blown Filter Layer	Polypropylene		Polypropylene Meltblown, white	Same
	Titanium dioxide			
Inner Non-Woven Layer	Polypropylene		Polypropylene Thermalbonded, white	Different Note 1
	Polyethylene			
Nose Support	Polyethylene		Polyethylene Coated Steel Wire	Different Note 1
	Polyethylene terephthalate			
	Iron			
Edge Wrap	Not Applicable		Polypropylene Spunbond, white or Polyethylene Terephthalate, white	Different Note 2
Ear Strings	Nylon	Nylon 6	Not Applicable	Different Note 1 and Note 4
		Carbon Black		
	Polyurethane			
Tie Strings	Not Applicable		Polypropylene Spunbond, white or Polyethylene Terephthalate, white	Different Note 3
Design Features				
Colors	• Model 202001629, 201703328, 202002107, and 201905891: White. • Model 201801049 and 201905443: Magenta, Yellow, Cyan, and Black.		Green (Outer)	Different Note 4
Style	Flat - Pleated		Flat - Pleated	Same
Multiple Layers	Yes		Yes	Same
Single Use	Yes		Yes	Same
Sterility				
Sterile	Non-Sterile		Non-Sterile	Same
Dimensions				
Length	• Model 202001629, 201703328, and 201801049: 210mm. • Model 202002107, 201905891, and 201905443: 220mm.		6.9” ± 0.2” (175.26mm ± 5.08mm)	Different Note 5

Width	• Model 202001629, 201703328, and 201801049: 85mm. • Model 202002107, 201905891, and 201905443: 80mm.	3.5" ± 0.3" (88.9mm ± 7.62mm)	Different Note 5
Technological Characteristics Product Barrier Specifications Per ASTM F2100 – Meets Level 3			
Particulate Filtration Efficiency (PFE)	Passed at ≥ 98% @ 0.1 micron (ASTM F2299)	Passed at ≥98% @ 0.1 micron (ASTM F2299)	Same
Fluid Resistance	Passed at 160mm Hg (ASTM F1862)	Passed at 160mm Hg (ASTM F1862)	Same
Bacterial Filtration Efficiency (BFE)	Passed at ≥ 98% (ASTM F2101)	Passed at ≥98% (ASTM F2101)	Same
Differential Pressure	Passed at < 6.0 mm H_2O/cm^2 (EN 14683:2019 Annex C)	Passed at <5 mmH_2O/cm^2 (MIL-M36954C)	Different Note 6
Flammability	Passed: Class 1 (16 CFR Part 1610)	Passed ≥3 Seconds burn time - Class 1 (16 CFR Part 1610)	Same
Biocompatibility			
In Vitro Cytotoxicity Test ISO 10993-5: 2009	Non-cytotoxic	Non-cytotoxic	Same
Skin Sensitization Test ISO 10993-10:2010	Non-sensitizing	Non-sensitizing	Same
Skin Irritation Test ISO 10993-10:2010	Non-irritating	Non-irritating	Same
Systemic Toxicity Test	Non-acute systemic toxicity	Not Applicable	Different Note 7

ISO 10993-11: 2017			

Comparison in Detail(s):

Note 1: Raw Material – Substantial Equivalence Assessments

The patient contacting material for the proposed device is different from predicate device. However, biocompatibility testing per ISO 10993 series standard requirements has been performed on the proposed device and the results does not show any toxicity effect. Performance testing with ASTM F2100-19 (Standard Specification for Performance of Materials Used in Medical Face Masks) has also been performed on the proposed device and the results show "pass" with meeting Level 3 requirements. Thus, this difference in materials is not assessed to raise different questions of safety and effectiveness compared to the predicate (K191355).

Note 2: Edge Wrap Component – Substantial Equivalence Assessments

The proposed device does not contain the "Edge Wrap" component of the predicate device. However, the "Edge Wrap" material of the predicate device, "Polypropylene Spunbond, white or Polyethylene Terephthalate, white" is the identical polypropylene or polyethylene terephthalate material that is included in mask layers of the proposed device.

- Without the predicate component of the Edge Wrap, the proposed device was evaluated with Performance testing with FDA's recognized standard of ASTM F2100-19 (Standard Specification for Performance of Materials Used in Medical Face Masks) with all favorable test results showing "pass" with meeting Level 3 requirements.
- As such, the minor difference of not having the "Edge Wrap" is not expected to raise different questions of safety and effectiveness compared to the predicate (K191355).

Note 3: Tie Strings Component – Substantial Equivalence Assessments

The predicate device is available in two types, ear string type and tie string type. The proposed device is provided in only the ear string type. Despite the absence of tie strings, tight securing with ear strings of the proposed device to the user's face, mouth, and nose is achieved as demonstrated with the favorable test results under the FDA's recognized standard of ASTM F2100-19 (Standard Specification for Performance of Materials Used in Medical Face Masks). Thus, this difference is not assessed to raise different questions of safety and effectiveness compared to the predicate (K191355).

Note 4: Colors – Substantial Equivalence Assessments

Colors for the proposed device is different from predicate device. However, biocompatibility testing per ISO 10993 series standard requirements has been performed on the proposed device and the results does not show any toxicity effect. Performance testing with ASTM F2100-19 (Standard Specification for Performance of Materials Used in Medical Face Masks) has also

been performed on the proposed device and the results show "pass" with meeting Level 3 requirements. Thus, this difference in colors is not assessed to raise different questions of safety and effectiveness compared to the predicate (K191355).

Note 5: Dimensions – Substantial Equivalence Assessments

Dimensions for the proposed device is different from the predicate device. However, performance testing with ASTM F2100-19 (Standard Specification for Performance of Materials Used in Medical Face Masks) has been performed on the proposed device and the results show "pass" with meeting Level 3 requirements. Thus, this difference in dimensions is not assessed to raise different questions of safety and effectiveness compared to the predicate (K191355).

Note 6: Differential Pressure – Substantial Equivalence Assessments

The differential pressure test reference used for the proposed device and the predicate device are not the same references; the differential pressure testing for the proposed device was conducted according to "EN 14683:2019 Annex C: Method for Determination of Breathability", while the differential pressure testing for the predicate device was conducted according to "MIL-M36954C: Military Specification-Mask, Surgical, Disposable".

- The differential pressure testing for the proposed device was appropriately completed for EN 14683:2019 Annex C. The EN 14683:2019 Annex C is the one of the mask performance standards specified in ASTM F2100-19. ASTM F2100-19 is the FDA's recognized consensus standard [FDA Recognition Number 6-425] which is the standard specification for performance of materials used in medical face masks.
- Thus, the standard reference difference of "EN 14683:2019 Annex C (Test Criteria: < 6.0 mm H_2O/cm^2) versus "MIL-M36954C (Test Criteria: < 5.0 mm H_2O/cm^2)" is not assessed to raise different questions in terms of the safety and effectiveness compared to the predicate device.

Note 7: Non-acute Systemic Toxicity Testing – Substantial Equivalence Assessments

Non-acute systemic toxicity biocompatibility testing per ISO 10993-11 has been performed on the proposed device and the results does not show any toxicity effect.

- However, non-acute systemic toxicity biocompatibility testing per ISO 10993-11 was not performed on the predicate device.
- The non-acute systemic toxicity biocompatibility testing per ISO 10993-11 performed on the proposed device does not raise different questions in terms of the safety and effectiveness compared to the predicate device.

8. Summary of Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks - Premarket Notification [510(k)] Submissions issued on March 5, 2004:

- ISO 10993-05:2009 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 10993-11:2017 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity
- ASTM F2100, Standard Specification for Performance of Materials Used in Medical Face Masks
- 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 Particulates Using Latex Spheres
- 16 CFR 1610, Standard for the Flammability of Clothing Textiles

Performance Testing			
Test Methodology	**Purpose**	**ASTM F2100-19 Acceptance Criteria: Level 3 Barrier**	**Result**
Particulate Filtration Efficiency (PFE) ASTM F2299-17	Measure initial particle filtration efficiency	≥98%	Passed
Fluid Resistance ASTM F1862-17	Evaluate the resistance to penetration by impact of small volume of synthetic blood	Pass at 160 mmHg	Passed
Bacterial Filtration Efficiency (BFE) ASTM F2101-19	Measure bacterial filtration efficiency	≥98%	Passed

Differential Pressure (mmH_2O/cm^2) EN 14683:2019 Annex C	Determine breathability of the mask	<6 mmH_2O/cm^2	Passed
Flammability 16 CFR Part 1610-2008	Response of materials to heat and flame	Class 1	Passed

Biocompatibility Testing

According to ISO 10993-1: 2018, the nature of body contact for the subject device is Surface Device category, Intact Skin Contact and duration of contact is B – prolonged (>24h to 30 d). The following tests for the subject device were conducted to demonstrate that the subject device is biocompatible and safe for its intended use:

Biocompatibility Evaluation			
Test Methodology	**Purpose**	**Acceptance Criteria**	**Result**
ISO 10993-5: 2009 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity.	Verify the Cytotoxicity potential of the subject device	Non-cytotoxic	Passed
ISO 10993-10: 2010 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization.	Verify the Sensitization potential of the subject device	Non-sensitizing	Passed
ISO 10993-10: 2010 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization.	Verify the Irritation potential of the subject device	Non-irritating	Passed
ISO 10993-11: 2017 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity.	Verify the Acute Systemic Toxicity potential of the subject device	Non-acute systemic toxicity	Passed

9. Summary of Clinical Testing

No clinical study is included in this submission.

10. Final Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, the GOOD High Fluid-Resistant Surgical Mask and the KOEASY High Fluid-Resistant Surgical Mask, is as safe, as effective, and performs as well as or better than the legally marketed predicated device, 3M™ High Fluid-Resistant Surgical Mask and 3M™ High Fluid-Resistant Procedure Mask, cleared under K191355.