510(k) Summary

1. SUBMITTER INFORMATION

Company Name:	WPT Corporation
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2. CORRESPONDENT INFORMATION

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3. DATE PREPARED: September 1, 2020

4. DEVICE NAME

Trade Name:	WPT Level 3 Surgical Mask; WPT Level 3 Procedure Mask
Common/Usual Name:	Surgical Face Mask
Classification Name:	Mask, Surgical
Regulation Number:	21 CFR 878.4040
Product Code:	FXX
Device Class:	Class II
Reviewing Panel:	General Hospital
Basis for Submission:	New device abbreviated 510k

5. PREDICATE DEVICE

Legally Marketed Equivalent Device

Manufacturer	Brand Name	510(k) Number
DemeTECH Corporation	DemeMASK Surgical Mask	K201469

6. DEVICE DESCRIPTION

The WPT Level 3 Surgical Mask and the WPT Level 3 Procedure Mask are flat-pleated style masks composed of three layers. The inner and outer layers are made of 100% Spunbound Polypropylene and the middle layer is made of 100% meltblown polypropylene filter media. Each mask contains ear loops or tie strings to secure the mask over the users' mouth and face and contain malleable nosepiece to provide a firm fit over the nose. Ear loops are made of latex free urethane elastic. The nose piece is made of malleable polypropylene covered aluminum to firmly fit over the nose. This device is not made from any natural rubber latex.
The masks are single use, disposable device, provided non-sterile.

7. DEVICE INDICATIONS FOR USE

The WPT Level 3 Surgical and Procedure 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.

8. **COMPARISON OF TECHNICAL CHARACTERISTICS**

Parameter	Proposed Device	Predicate Device	Comparison
Manufacturer		Demetech Corporation	
510(k)		K201479	
Regulation Name	Surgical Apparel	Surgical Apparel	Same
Device Classification Name	Mask, Surgical	Mask, Surgical	Same
Classification	Class II, FXX, 21 CFR 878.4040	Class II, FXX, 21 CFR 878.4040	Same
Indications for Use	The WPT Level 3 Surgical Mask and WPT Level 3 Procedure 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 the potential exposure to blood and body fluids. This is a single use, disposable device 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 provided non-sterile.	Same
Mask Style	Flat-Pleated	Flat-Pleated	Same
Materials			
Outer Facing Layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
Middle Layer	Melt Blown Polypropylene Filter	Melt Blown Polypropylene Filter	Same
Inner Facing Layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
Nose Piece	Aluminum strip with polypropylene covering	Single Galvanize Wire, Coated By PE	Similar
Ear Loop/Ties	Urethane elastic - Not made with natural Rubber Latex	Spandex and Nylon- Not made from natural rubber latex	Similar
Color	White		Same
Dimension (Width)	3 ¾" x 6 ¾ "	175mm x 95 mm	Similar
OTC Use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same

Parameter	Proposed Device	Predicate Device	Comparison
Use	Single Use	Single Use	Same
Performance			
Fluid Resistance Performance ASTM F 1862 –	Pass at 160 mmHg	Pass at 160 mmHg	Same
Particulate Filtration Efficiency ASTM F2299	Pass at 99.8%	Pass at 99%	Similar
Bacterial Filtration Efficiency (BFE) ASTM F2101	Pass at 99.8%	Pass at 99%	Similar
Differential Pressure MIL-M-36954C	4.3 mm H_2O/cm^2	3.6 mm H_2O/cm^2	Similar
Flammability 16 CFR 1610	Class 1	Class 1	Same
Biocompatibility ISO 10993-5 and ISO 10993-10	Under the conditions of the studies employed. The device is non-cytotoxic, non-sensitizing, and non-irritating	Under the conditions of the studies employed. The device is non-cytotoxic, non-sensitizing, and non-irritating	Same

9. Table of Conformity to Standards

Test	Purpose
ASTM F1862/F186M-17	Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
ASTM F2100-19	Standard Specification for Performance of Materials Used in Medical Face Masks
ASTM F2299	Standard Test Method for Determining the Initial Efficiency of materials Used in face Masks to Penetration by Particulates Using Latex Spheres
ASTM F2101 BFE	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials Using a Biological Aerosol of Staphylococcus aureus
MIL-M-36954C EN 146583 :2019 Edition Annex C	Differential Pressure (Delta P)
16 CFR 1610	Flammability

8. SUMMARY OF NON-CLINICAL TESTING

Table of Performance Testing – Bench

Test	Purpose	Acceptance Criteria per ASTM F2100-11 Level 3 (AQL=4.0%	Test Results	
			Test Results ASTM F2100-11 Level 3	Average
ASTM F1862 Synthetic Blood	Determine synthetic blood penetration resistance	29 out of 32 pass at 160 mmHg	Pass (30/32)	N/A
Particulate Filtration Efficiency ASTM F2299	Determine sub micron particulate filtration efficiency	≥98%	Pass	99.84%
ASTM F2101 BFE	Determine bacterial filtration efficiency	≥98%	Pass	99.86%
MIL-M-36954C Delta P EN 146583:2019 Edition Annex C	Determine breathing resistance or differential pressure	< 5.0 mm H_2O/cm^2	Pass	4.3 mm H_2O/cm^2
CPSC 1610 Flammability	Determine flammability or flame spread	5/5 Passed ≥3.5 seconds burn time Class 1	Pass	IBE (Ignited but extinguished)

Table of Biocompatibility Testing

The surgical face mask is identified as

- Intact skin
- Limited (<24h)

The FDA recommended test are:

- cytotoxicity,
- sensitization,
- Irritation or Intracutaneous Reactivity

Test	Standard	Results
Cytotoxicity	ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	PASS
Irritation	ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	PASS
Sensitization	ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	PASS

No clinical study is included in this submission

10. CONCLUSION

The non- clinical tests demonstrates 4583 that the subject device is as safe, as effective and performs as well as the predicate device and is substantially equivalent.