September 12, 2022

Plasmatica LTD
% Vaibhav Rajal
Official Correspondent for Plasmatica LTD
MDI Consultants Inc
55 Northern Blvd
Great Neck, New York 11021

Re: K221533
Trade/Device Name: Plasma Shield
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, OCT
Dated: May 2, 2022
Received: May 27, 2022

Dear Vaibhav Rajal:

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

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General 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)*
K221533

Device Name
Plasma Shield

Indications for Use *(Describe)*
The Plasma Shield is to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens

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

The assigned 510(k) number is K221533

1. Submitter's Identification:

Plasmatica LTD.
HaTa'asiya ST 25 Ra'anana,
Israel,
4365413.

Contact Person: Mr. Adam Sagiv
Chief Executive Officer and Founder
Telephone: +972-52-2232562
Email: Adam@plasmatica.com

Date Summary Prepared: September 8, 2022

2. Name of the Device:

Trade Name: Plasma Shield
Regulation Number: 21 CFR 876.1500
Regulatory Class: Class II
Product Code: OCT, GCJ

3. Information for the 510(k) Cleared Device (Predicate Device):

FDA Product Code	Common Name	Regulation Number
OCT	Anti-Fog Solution And Accessories, Endoscopy	876.1500
GCJ	Laparoscope, General & Plastic Surgery	876.1500

4. Device Description:

The Plasma Shield is intended to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens. The Plasma Shield device is designed for reducing laparoscopic lens fogging by performing cold plasma treatment of a laparoscope lens. The Plasma Shield device is a cold plasma-based device to be used in an operating room, prior to and during laparoscopic procedures. The cold plasma creates a super hydrophilic scope lens surface after treatment (aka activation). The device does not interact directly with the patient's body.

The Plasma Shield consists of these components and accessories:

- The main system is a Reusable Part (RP) that generates the cold plasma required to treat the scope for defogging.
- A Disposable Part (DP) – a single-use, sterilized component interfacing with the scope itself and used for each procedure (can be used multiple times within the

same procedure for the same patient). The DP assembly includes a folded surgical drape and packaged in a pouch.

A single-use, sterile anti-fog solution and foam is supplied together with the Disposable Part.

5. Indications for Use:

The Plasma Shield is to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens

6. Comparison to the 510(k) Cleared Devices (Predicate Devices):

Table of Comparison to Legally Marketed Device and Discussion of Similarities and Differences:

The proposed subject device is being compared to the predicate devices identified under Section 1(i): Identification of Legally Marketed Device Which We Claim Substantial Equivalence;

Parameters	Subject Device	Primary Predicate Device	Reference Predicate Device	Similarities or Differences
Device Name	Plasma Shield	Scope Antifogging System/See Sharp	DHELP/Clearify	
Manufacturer	Plasmatica Ltd.	Xodus Medical, Inc.	New Wave/Medtronic	
Regulatory Pathway	510(k)	510(k)	510(k)	Same
510(k)/De Novo number	TBD	K182080	K062779	
Classification	II	II	II	Same
Product Code	GCJ, OCT	GCJ, OCT	GCJ, OCT	Same
Regulation Number	876.1500	876.1500	876.1500	Same
Regulation Name	Endoscope and accessories	Endoscope and accessories	Endoscope and accessories	Same
Regulation Medical Specialty	Gastroenterology/Urology	Gastroenterology/Urology	Gastroenterology/Urology	Same
Panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	Same
Intended Use	The Plasma Shield is to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens	The Scope Antifogging System is intended use for this device is to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the endoscope and laparoscope lens.	DHELP is intended to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the endoscope and laparoscope lens.	Similar
Technological Characteristics	1) Mechanism of Action involves Cold Plasma	1) Mechanism of Action involves heating and	1) Mechanism of Action involves heating and	See NOTE 1

	treatment of a laparoscope lens. 2) Uses antifog solution. 3) Compact device that enables intra-abdominal visibility in laparoscopic procedures. 4) Consists of a reusable main system, disposable part (sterile) with Anti-Fog solution and sponge applicator (both sterile). 5) Compatible with laparoscopes of 5mm to 10mm.	dipping of distal end of endoscope/laparoscope into solution 2) Uses antifog solution 3) Compact device that enables intra-abdominal visibility in laparoscopic procedures 4) Device is small, sterile, and disposable with Anti-Fog solution, sponge, and trocar wipes (sterile). 5) Compatible with laparoscopes of 5mm to 12mm.	dipping distal end of endoscope into solution. 2) Uses antifog solution. 3) Compact device that enables intra-abdominal visibility in laparoscopic procedures. 4) Device is small, sterile, and disposable with Anti-Fog solution, sponge applicator and trocar wipes (sterile). 5) Compatible with laparoscopes of 5mm to 10mm.	
Performance testing	Testing conducted with live anesthetized pig. A Stryker endoscopy system was used with a 10mm and 5mm Stryker scope, and Plasma Shield was evaluated in a series of experiments. Risk analysis, Biocompatibility (ISO 10993-1), Sterilization, Electrical and EMC based on IEC 60601-1-2 and 60601-1, SW V&V, bench testing, Life Expectancy Verification, Lens Fogging Validation, usability simulated use testing to demonstrate effectiveness in a surgical environment simulation chamber.	Testing conducted with live anesthetized pig. A Karl Storz endoscopy system was used with a 5mm and 10mm Storz laparoscope. A series of exploratory procedures with 4 different Storz laparoscope types were used. Cleaning and application of antifogging solution to the scopes for determination of fogging prevention was performed in several instances. Lens Fogging Validation, Lens Wiping of Debris Validation, Life Expectancy Validation, Trocar Wiping Validation, Biocompatibility, Electrical Safety and EMC testing were also conducted.	Testing conducted with live anesthetized pig. A Stryker 888 endoscopy system was used with a 10mm and 5mm Stryker laparoscope, and DHELP was evaluated in series of experiments with varying temperatures and surfactant concentrations and by comparison to the current defogging methods. DHELP was also used with 4 different laparoscope types and on Olympus, Stryker and Storz camera systems to make sure that it was functionally compatible with the most common scopes and systems. Temperature testing was conducted on the DHELP device. Risk Analysis and biocompatibility testing were also conducted.	See NOTE 2
Clinical Studies	Not conducted	Not conducted	Not conducted	Similar
Compatibility with the environment and other devices	Compatible with endoscope and laparoscope	Compatible with endoscope and laparoscope	Compatible with endoscope and laparoscope	Similar
Energy used and/or delivered	RF	Heat radiation	Heat (Infrared) radiation	See NOTE 3
Where used (hospital, home, ambulance, etc.)	Hospitals and/or surgery centres on or by the order of a physician	Hospitals and/or surgery centres on or by the order of a physician	Hospitals and/or surgery centres on or by the order of a physician	Same
Design performance	Cell batteries at 11.1V and a BMS (battery management system) and a Li-Ion battery charger (the charger charges the	Cell Battery No charger	Cell Battery No charger	See NOTE 4

	Li-Ion Battery pack of the device) 12.6V and 0.5A and DC power jack. When the device is being charged, it is turned off by design.			
Electrical safety	Electrical safety and EMC compatibility testing was successfully conducted on the Scope Antifogging System. The system complies with the IEC 60601-1-2 standard for EMC. The Scope Antifogging system was electrical safety tested under the Standard IEC 60601-1.	Electrical safety and EMC compatibility testing was successfully conducted on the Scope Antifogging System. The system complies with the IEC 60601-1-2 standard for EMC. The Scope Antifogging system shall be electrical safety tested under the Standard IEC 60601-1.	No information available	
Materials, Biocompatibility, and Chemical Safety	Biocompatible plastics housing FDA approved Anti-fog solution kit	Biocompatible plastics housing Anti-fog solution: Water, Isopropanol, Ethanol, Surfactant	Biocompatible plastics housing FDA approved ShurClens wound cleaning surfactant	Similar
Similarities to Subject Device	NA	Intended Use and compatibility with scopes of 5mm to 12mm	Intended Use and compatibility with scopes of 5mm to 10mm	Similar
Weight	1 kg max	No information available	155 g	
Dimensions	15*10*7 cm	No information available	9*7*6 cm	
Sterilization	ETO	Gamma Radiation	Gamma Radiation	See NOTE 2
Operating environmental conditions	Temp: 10-40ºC Rel Humid: 20-80% Atm Pres: 90-106 kPa	Temp: 5-40ºC Rel Humid: 15-95% Atm Pres: 70-106 kPa	No information available	Similar

Discussion of Similarities and Differences between the proposed subject device and both the primary and reference predicate devices.

Comparison of intended use

Plasma Shield and predicate have identical indications for use.
Plasma Shield and predicate have an identical primary intended use.

Technological Characteristic Comparison to Predicate

Comparison in Detail(s):

NOTE 1: Plasma Shield does not raise any additional risk to the patient when applied on commercially available laparoscopes comprised of stainless steel and glass. The subject device mechanism of action utilizes Cold Plasma while the predicate and reference device mechanism of action uses heat for introducing the fogging effect. Cold plasma treatment has a long (over 25 years) history of safe use in medical applications, i.e., sterilization of medical devices made of stainless steel and glass.

In addition to a disposable part, the subject device has a reusable part, which is not the case of the predicate and reference devices. This fact raises no additional safety concern since the reusable part was fully validated for cleaning and is fully in compliance with the TIR30 reusable standard requirements. The reusable device is covered by a sterile drape in-between use.

Cleaning Validation:

Manual cleaning process validation for the Plasma Shield reusable device, based on our Study, was performed and passed testing in accordance with TIR30.

Ingress tests:

A ingress test was performed for determining the viability of organisms after being exposed to the Single Use part of the Plasma Shield multiple times, at worst case system operation conditions, concluded that all test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211, and 820.

NOTE 2: The following tests for Electrical and EMC based on IEC 60601-1-2 and 60601-1, SW V&V, and usability simulated use testing were conducted in addition to the special controls conducted on the predicate device:

Software Verification and Validation Testing
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Minor" level of concern.

Usability Study Report

All the subjects succeeded to perform the device related tasks, with minimal number of requests for assistance and with no errors or inefficiencies. Following the summarized results, it can be concluded that the study success criteria was completely met, and that the Plasma Shield device can be easily operated by the potential end users and used safely according to the instructions manual.

Animal testing to demonstrate effectiveness in porcine model report: "Comparison of Plasma Shield vs. Clearify, Anti-fogging Devices, and Using Laparoscopy in Swine" was conducted and included in the submission.

The results of the risk analysis (according to ISO 14971) performed on Plasma Shield is detailed in the Plasma Shield Risk Analysis Report.

The subject device is categorized per Annex A of ISO 10993-1 as a medical device with no body contact. No further testing is deemed necessary. This difference has no impact on the device safety, since all device materials are well categorized, and biologically evaluated.

An ETO Sterilization validation (according to ISO 11135) was performed in the study titled EO Sterilization Validation for Clarity One of Plasmatica Ltd.

NOTE 3:

With regards to the use of radio frequency, Plasma Shield does not raise any additional risk to the patient. Plasma Shield conforms to the requirements of IEC 60601-1-2 and 6061-2-2 sections 202.7 and 202.8.

NOTE 4:

The predicate, reference, and subject devices use regular disposable batteries. The subject device, in addition, uses a Li-Ion battery charger, 12.6V and 0.5A and DC power jack. This fact raises no additional safety impact on the user. The Li-Ion battery is widely used in medical devices in a similar environment. It was tested and is fully compliant with the IEC 623166 standard under test report IEC 62133-2 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems.

Conclusions:

Comparison with the predicate and reference devices regarding functional characteristics shows that the subject device is intended for equivalent procedures as compared to the predicate and reference devices and makes use of similar functionality. The technological differences do not raise additional safety issues.

Substantial Equivalence Conclusion: The Sponsor has demonstrated through performance testing, design and features, and non-clinical testing, that the proposed subject device is substantially equivalent to the predicate and reference predicate devices.

The subject device Plasma Shield is Substantially Equivalent to the predicate and reference predicate devices.

7. Electrical and EMC Testing

The following testing supports testing information demonstrating safety and effectiveness of the Plasma Shield Device in the intended environment of use:

- FR Number 19-4 07/09/2014 ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- FR Number 19-8 09/17/2018 IEC 60601-1-2- Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- FR Number 6-389 06/07/2021 IEC 60601-2-2 Edition 6.0 2017-03 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories. Sections 202.7, 202.8 ONLY

8. Performance Testing:

Bench Performance testing was conducted on the proposed subject device to determine the performance and efficacy of the device. In addition, Performance testing – animal was conducted on the proposed subject device to compare the anti-fogging effect of Plasma Shield vs. Clearify™ devices during laparoscopy in swine. The study demonstrated the anti-fogging effect for both the proposed subject device and the predicate device.

Validation of product performance in compliance with the following product specification requirements was conducted on the proposed subject device:

- PRSJ.02: Scope's lens surface characteristics immediately post treatment (aka activation): Plasma-induced surface activation should create a hydrophilic scope lens surface to reduce scope lens fogging as effectively as the predicate device, thereby demonstrating substantial equivalence.
- PRS 4.3: The Plasma Shield interfaces with laparoscopes of 5mm and 10mm diameter, with 0-45 angles.
- PRS H.07: The system shall perform lens activation for scopes of 0, 30, and 45 angles, and different materials

The Plasma activated lenses of all tested scope are Super Hydrophilic and comparison to untreated lenses show highly improved contact angles. Product performance comply with the specification requirements. Therefore, plasma surface activation induced hydrophilicity reduces scope lens fogging, conferring substantial equivalence with the predicate device working mechanism. Comparison with the predicate and reference devices regarding functional characteristics shows that the subject device is intended for equivalent procedures as compared to the predicate and reference devices and makes use of similar functionality.

Comparison of Proposed Subject Device Plasma Shield Vs. Clearify Predicate Device, Anti-Fogging Devices was conducted during Laparoscopy in Swine to compare the anti-fogging hydrophilicity effect of Plasma Shield vs. Clearify™ devices during laparoscopy in swine in order to demonstrate substantial equivalence.

Overall, both Plasma Shield and Clearify scope pretreatment received a higher score compared to none treated scope following video evaluation in all experimental conditions tested. These suggest that pretreatment of the scope with Plasma Shield or Clearify was more effective in preventing fog formation on the scope during laparoscopy compared to no treatment in these experimental settings. It can be concluded that Plasma Shield scope pretreatment is comparable to Clearify in its effectiveness to prevent fogging on the scope during laparoscopy and both are better in grading than no treatment, therefore demonstrating substantial equivalence between the devices.

9. Usability Studies

Usability Testing was conducted on the proposed subject device as per IEC 62366-1:2015, per FDA Guidance “Applying Human Factors and Usability Engineering to Medical Devices” February 2016 and ANSI/AAMI NS4 2013 (R)2017. In addition, the proposed subject device is in compliance with the IEC 60601-1-6 – Collateral Standard – Usability test standard.

10. Sterilization and Product Shelf Life

The proposed subject device is composed of a reusable part (RP) and disposable part (DP). The DP is sealed and the sterile part contains electrodes intended to deliver the plasma to the scope. The following validations have been conducted on the proposed subject device:

Test Name	Main standard/guideline	Essence	DP level	RP level	System level
Sterilization validation	ISO 11135	Conduct testing to ensure compliance to sterilization standard (ETO)	✓		
Packaging validation DP	ISO 11607-1	Conduct packaging integrity, storage and transportation tests per appropriate standards	✓		
Shelf-life validation	ASTM F 1980:2016	Conduct shelf-life tests per appropriate standard to verify required device shelf life.	✓		
Packaging, shipping and environment	ASTM D4169-16 ASTM D4332-14	Shipping performance and environmental testing	✓	✓	

11. Product Cleaning/Disinfection Information

The proposed subject device is composed of a reusable part (RP) and disposable part (DP). The RP cleaning validation was performed to validate the cleaning process for the entire external surface of the device.

12. Software information:

Software verification and validation testing were conducted and supported by documentation according to the FDA's Guidance for Industry and FDA Staff "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. Based on FDA Software level of concern, the subject device is classified as "Minor" level of software concern.

The details about the software were clearly demonstrated in the software documentation and the risks related to the software products were mitigated

13. Risk Analysis

The proposed subject Plasma Shield Device complies with the ISO 14971: 2019 Medical devices - Application of risk management to medical devices" test standard. The testing ensures that the proposed subject device "Plasma Shield" meets the appropriate safety and effectiveness requirements.

14. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the proposed subject Plasma Shield Device in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance requirements.

- IEC 62133-2 Edition1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems
- ISO 11607-1: 2019 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F1886/F1886M - 2016 - Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- FR Number 14-482 06/27/2016 ASTM F88/F88M-15- Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1140/ F1140M-13 (2020) Standard Test Methods for Packages Internal Pressurization Failure Resistance of Unrestrained
- ASTM F1929-15 - Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F3039-15 - Standard Methods in Nonporous Packaging or Flexible Barrier materials by Dye Penetration
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems. Sections 14, 15 NOT APPLICABLE
- ASTM D4332-14 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
  **Additional compliance to US-FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" of 4th September 2020.
- ISO 15223-1: 2016 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements
- AAMI TIR12:2020 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- AAMI TIR30:2011/(R)2016 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that the proposed subject Plasma Shield Device tested met all relevant requirements of the aforementioned tests.

Conclusions:

The design, characteristics, and performance of the proposed subject Plasma Shield device substantiates that the device is working as intended (use prior to and during endoscopic and laparoscopic procedures to prevent the fogging of the scope lens).
The proposed subject Plasma Shield Device is substantially equivalent to both its primary predicate device and the reference predicate device.