December 23, 2020

Plasdent Corporation
Belen Walayat
Corporate Manager
969 Price Street
Pomona, California 91767

Re: K201604
Trade/Device Name: Plasdent Disposable Barrier Sleeves and Barrier Film
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape And Drape Accessories
Regulatory Class: Class II
Product Code: PEM
Dated: November 18, 2020
Received: November 27, 2020

Dear Belen Walayat:

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,

Clarence W. Murray, III, Ph.D.
Acting 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: 0613012020
See PRA Statement below.

510(k) Number *(if known)*
K201604

Device Name
Plasdent Disposable Barrier Sleeves and Barrier Film

Indications for Use *(Describe)*

Plasdent Disposable Barrier Sleeves and Barrier Film are intended to be used as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient one time use only.

Model#	Description	Designed For
PS201	B Tray Sleeves w/ Lock Top	Dental Instrument Tray, 10-1/2" x 14"
PS202	A Tray Sleeves w/ Lock Top	Dental Instrument Tray, 11-5/8" x 14-1/2"
PS204	F Tray Sleeves w/ Lock Top	Dental Instrument Tray, 7-1/2" x 10-1/2"
PS3800	Half Chair Covers or Sleeves	Half Dental Chair, 27-1/2"W x 24"L
PS3825	Wide Half Chair Cover	Wide Half Chair, 32”W x 32”L
PS102	Half Chair Cover	Half Chair, 24”W x 32”L
PS106	Full Chair Covers or Sleeves	Wide Full Dental Chair, 44"W x 54"L
PS3850	Full Chair Covers or Sleeves	X-Long Full Chair, 29"W x 80"L
PS650	Headrest Cover	Headrest, 9-1/2"W x 11"W
PS660	Headrest Cover	Large Headrest, 10"L x 14"W
PS1250C	Sticky Wraps (Barrier Film)	4"W x 6"L, Clear Color
PS1250B	Sticky Wraps (Barrier Film)	4"W x 6"L, Blue Color
PS400	Computer Covers	Keyboard cover, 22"W x 14"L
PS400-S	Computer Covers	Small Keyboard, 12-1/2"W x 8"L
PF405	Computer Covers	PC Mouse, Universal
PS410	Computer Covers	LCD + Keyboard 22"W x 26"L
PS425	Computer Covers	Laptop, 15-2/3"W x 24"L
PS1100	X-ray Cover	X-ray 24"W x 32"L
PS1105	X-ray Cover	X-ray, Universal, 15"W x 26"L
PS328P	Lite Handle Cover	Lite Handle for T-Style 5-3/4"W x 4"L
PS320A	Air/Water Syringe Covers	Air/Water Syringe, 3"W x 10"L
PS3720	Air/Water Syringe Covers	Air/Water Syringe, Tube 2" Diameter

PS3740	Air/Water Syringe Covers	Air/Water Syringe, Tube 4" Diameter
PS520	Sensor Cover	#2 Sensor Cover, 1-5/8"W x 8-3/8"L
PS530	Sensor Cover	#0 Sensor Cover, 1-3/8"W x 8-3/8"L
PS-SUNI-2	X-ray Sensor Sheaths	For SUNI Size 2 Compatible TIDI: 20819
PS-DEXIS-2	X-ray Sensor Sheaths	For DEXIS Size 2 Compatible TIDI: 20999
PS-6100-0	X-ray Sensor Sheaths	For KODAK 6100 Size 0 Compatible TIDI: 20977
PS-6100-1	X-ray Sensor Sheaths	For KODAK 6100 Size 1 Compatible TIDI: 20978
PS-6100-2	X-ray Sensor Sheaths	For KODAK 6100 Size 2 Compatible TIDI: 20979
PS-GXDR-1	X-ray Sensor Sheaths	For GENDEX/XDR Size 1
PS-GXDR-2	X-ray Sensor Sheaths	For GENDEX/XDR Size 2
PS-SHICK-1	X-ray Sensor Sheaths	For SCHICK Size 1 Compatible TIDI: 20824
PS-SHICK-2	X-ray Sensor Sheaths	For SCHICK Size 2 Compatible TIDI: 20825
PS4550	Curing Light Sleeves	Curing Light Handle, 5"W x 10"L
PS4660	Curing Light Sleeves	Complete Curing Light Handle, 3-1/4"W x 12"L
PS-DEMI	Curing Light Sleeves	Curing Light for DEMI
PS-LED	Curing Light Sleeves	LED Curing Light, 3-1/4"W x 12"L
PS700	Handpiece Covers	Low Speed Long H.P., 1-1/2"W 7-1/2"L
PS710	Handpiece Covers	Low Speed Contra-Angle, 8"W 3-1/2"L
PS720	Handpiece Covers	High Speed, 1-1/6"W x 7-3/4"L

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 K201604

I. SUBMITTER:

Plasdent Corporation
969 Price Street
Pomona, CA 91767
Contact Person: Belen G. Walayat
Title: Corporate Manager
Phone: (909)620-0289*106
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Summary prepared: 01/30/2019

Summary revised: 08/19/2020

II. DEVICE

Name of Device: Plasdent Disposable Barrier Sleeves and Barrier Film

Regulation Number: 21 CFR 878.4370

Common Name: Dental Barriers and Sleeves

Classification Name: Surgical drape and drape accessories

Regulatory Class: II

Product Code: PEM

III. PREDICATE DEVICE

Predicate device: Pac-Dent Barrier Sleeve, Cover-It™ Barrier Film- **K151123**

Subject Device: Plasdent Disposable Barrier Sleeves and Barrier Film- **K201604**

IV. DEVICE DESCRIPTION

Plasdent Disposable Barrier Sleeves and Barrier Film are made of polyethylene film (PE), and come in various shapes and sizes as dental accessories intended to fit over and cover dental instruments and equipment. The Disposable Barrier Sleeves cover small hand-held dental instruments such as air/water syringes, curing lights, hand pieces, computers, sensors, dental instrument trays, and other similar hand-held instruments to provide as a physical barrier or cover during a dental procedure. In other forms, the

Disposable Barrier Film Covers are used to cover equipment, such as dental chairs, headrests, X-Ray heads, and other devices. The device is non-sterile, prepackaged, and is disposable, for single patient and one time use only.

V. INDICATIONS FOR USE

Plasdent Disposable Barrier Sleeves and Barrier Film are intended to be used as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only.

Model#	Description	Designed For
PS201	B Tray Sleeves w/ Lock Top	Dental Instrument Tray, 10-1/2" x 14"
PS202	A Tray Sleeves w/ Lock Top	Dental Instrument Tray, 11-5/8" x 14-1/2"
PS204	F Tray Sleeves w/ Lock Top	Dental Instrument Tray, 7-1/2" x 10-1/2"
PS3800	Half Chair Covers or Sleeves	Half Dental Chair, 27-1/2"W x 24"L
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PS102	Half Chair Cover	Half Chair, 24”W x 32”L
PS106	Full Chair Covers or Sleeves	Wide Full Dental Chair, 44"W x 54"L
PS3850	Full Chair Covers or Sleeves	X-Long Full Chair, 29"W x 80"L
PS650	Headrest Cover	Headrest, 9-1/2"W x 11"W
PS660	Headrest Cover	Large Headrest, 10"L x 14"W
PS1250C	Sticky Wraps (Barrier Film)	4"W x 6"L, Clear Color
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PS400-S	Computer Covers	Small Keyboard, 12-1/2"W x 8"L
PF405	Computer Covers	PC Mouse, Universal
PS410	Computer Covers	LCD + Keyboard 22"W x 26"L
PS425	Computer Covers	Laptop, 15-2/3"W x 24"L

PS1100	X-ray Cover	X-ray 24"W x 32"L
PS1105	X-ray Cover	X-ray, Universal, 15"W x 26"L
PS328P	Lite Handle Cover	Lite Handle for T-Style 5-3/4"W x 4"L
PS320A	Air/Water Syringe Covers	Air/Water Syringe, 3"W x 10"L
PS3720	Air/Water Syringe Covers	Air/Water Syringe, Tube 2" Diameter
PS3740	Air/Water Syringe Covers	Air/Water Syringe, Tube 4" Diameter
PS520	Sensor Cover	#2 Sensor Cover, 1-5/8"W x 8-3/8"L
PS530	Sensor Cover	#0 Sensor Cover, 1-3/8"W x 8-3/8"L
PS-SUNI-2	X-ray Sensor Sheaths	For SUNI Size 2 Compatible TIDI: 20819
PS-DEXIS-2	X-ray Sensor Sheaths	For DEXIS Size 2 Compatible TIDI: 20999
PS-6100-0	X-ray Sensor Sheaths	For KODAK 6100 Size 0 Compatible TIDI: 20977
PS-6100-1	X-ray Sensor Sheaths	For KODAK 6100 Size 1 Compatible TIDI: 20978
PS-6100-2	X-ray Sensor Sheaths	For KODAK 6100 Size 2 Compatible TIDI: 20979
PS-GXDR-1	X-ray Sensor Sheaths	For GENDEX/XDR Size 1
PS-GXDR-2	X-ray Sensor Sheaths	For GENDEX/XDR Size 2
PS-SHICK-1	X-ray Sensor Sheaths	For SCHICK Size 1 Compatible TIDI: 20824
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PS4550	Curing Light Sleeves	Curing Light Handle, 5"W x 10"L
PS4660	Curing Light Sleeves	Complete Curing Light Handle, 3-1/4"W x 12"L
PS-DEMI	Curing Light Sleeves	Curing Light for DEMI
PS-LED	Curing Light Sleeves	LED Curing Light, 3-1/4"W x 12"L
PS700	Handpiece Covers	Low Speed Long H.P., 1-1/2"W x 7-1/2"L

PS710	Handpiece Covers	Low Speed Contra-Angle, 8"W x 3-1/2"L
PS720	Handpiece Covers	High Speed, 1-1/6"W x 7-3/4"L

VI. TECHNOLOGICAL CHARACTERISTICS COMPARISON

The subject device, Plasdent Disposable Barrier Sleeves and Barrier Film, and the predicate device, Pac-Dent Barrier Sleeve, Cover-It™ Barrier Film, have the same intended use, which are used as protective barriers intended to fit over and cover dental instruments and equipment. Both the subject device and predicate device are made of same material, which is polyethylene film (PE). Both are non-sterile, prepackaged, disposable, and are for single patient and one time use only. The main slight difference between the subject and predicate device is the material composition. The polyethylene film of the subject device is composed of 30% low density polyethylene (LDPE) and 70% linear low density polyethylene (LLDPE), while the predicate device is composed of 20% low density polyethylene (LDPE) and 80% linear low density polyethylene (LLDPE). The difference is negligible & within acceptable range.

DEVICE	**Subject Device** Plasdent Disosable Barrier Sleeves and Barrier Film (K201604)	**Primary Predicate Device** Pac-Dent Barrier Sleeve, Cover-It™ Barrier Film(K151123)	**Comparison**
Intended Use	To be used as a barrier for dental instruments and equipment.	To be used as a barrier for dental instruments and equipment.	Same
Classification Product Code	PEM	PEM	Same
Material	Polyethylene film	Polyethylene film	Same
Material Composition	LLDPE (70%) LDPE (30%) Blue pigment (item#PS1250B) Adhesive (item#PS1250B, PS1250C)	LLDPE(80%) LDPE (20%) Blue pigment (item#100B, C101B) Adhesive (item#C101, C101B)	Similar

Biocompatibility	Non-cytotoxic Non-sensitizing Non-irritating	Non-cytotoxic Non-sensitizing Non-irritating	Same .
Specifications and Tolerances	Paper backing: none Film thickness:0.02-0.06mm Tolerance: <0.01mm	Paper backing: some of the model Film thickness:0.02-0.06mm Tolerance: <0.01mm	Similar
Mechanical Properties	Tensile Strength –ASTM D882-Subject device is equivalent to predicate device.	Tensile Strength –ASTM D882	Same Pass
	Resistance to Puncture -ASTM F1342-Subject device is equivalent to predicate device. Tear Strength – ASTM D1424-Subject device is equivalent to predicate device. Effectiveness of X-Ray and Sensor Devices covered with Barrier devices.	Resistance to Puncture- ASTM F1342 Tear Strength – ASTM D1424	Same Pass Same Pass Same Pass
Performance Properties	Synthetic Blood Penetration-Pass	Synthetic Blood Penetration-Pass	Same Pass
Sterility	Non-sterile	Non-sterile	Same
Single Use	Single use device	Single use device	Same
FDA-Recognized Standards	ASTM F1670 ASTM F1671 ASTM D882-18 ASTM F1342 ASTM D1004-13 ISO 10993-5 ISO 10993-10 ISO 6988-13	ASTM F1670 ASTM F1671 ASTM D882-18 ASTM F1342 ASTM D1004-13 ISO 10993-5 ISO 10993-10 ISO 6988-13	Same

VII. SUMMARY OF NON-CLINICAL TESTING

Shown below is the non-clinical testing performed with the subject device to demonstrate that the device can meet the acceptance criteria referenced standard or test methodology shown in the table below:

TEST	STANDARD	PURPOSE	ACCEPTANCE CRITERIA	RESULTS	RESULTS SUMMARY
BIOCOMPATIBILITY TESTING:					
In-Vitro Cytotoxicity	ANSI/AAMI/ISO 10993-5	Evaluate the cytotoxicity of a test article extract.	If viability is reduced to <70% of the blank, it has a cytotoxic potential.	Text extract 100%: Viab. 79.10% Test extract 75%: Viab. 83.72% Test extract 50%: Viab. 88.91% Test extract 25%: Viab. 94.10%	No cytotoxicity potential.
Sensitization	ISO 10993-10	Evaluate the potential of the test article to cause delayed dermal contact sensitization in a guinea pig maximization test.	Magnusson and Kligman grades of 1 or greater in the test group indicate sensitization.	All dermal reactions for all treatment groups over 24 and 48 hours: 0	Not considered a sensitizer in the guinea pig maximization test.
Irritation	ISO 10993-10	Evaluate the potential of the test article to cause skin irritation following application on the skin or rabbits.	Cumulative irritation index mean score >0.5 indicate irritation.	Overall Test Group Mean: 0	Irritation response category of test article classified as Negligible.
PERFORMANCE TESTING:					
Tensile Strength	ASTM D882-18	Determine the tensile properties of Subject device's disposable barrier sleeve compared to that of Predicate device disposable barrier sleeve.	Transverse: 35-45 MPa Lengthways: 23-28 MPa	HL181201: T 39.46, L 26.26 HL20190601: T 39.84, L 26.46 HL20190605: T 40.32, L 26.52	The tensile strength of both products is in the same range.
Puncture Resistance	ASTM F1342-05	Determine the puncture resistance of Subject device's disposable barrier sleeve compared to that of Predicate device's disposable barrier sleeve.	4N-5N	20190528: 4.56N 20190601: 4.58N 20190605: 4.56N	The puncture resistance of both products is in the same range.
Tear Resistance	ASTM D1004-13	Determine the tear resistance of Subject device's disposable barrier sleeve compared to that of Predicate device's disposable barrier sleeve.	4N-6N	HL20190605: 5.026N HL20190610: 5.046N HL20190615: 5.032N	The tear resistance of both products is in the same range.

Synthetic Blood Penetration	ASTM F1670	Evaluate the resistance of test material to penetration by synthetic blood under conditions of continuous liquid contact.	Pass determination based on no visual detection of synthetic blood penetration.	Material: no synthetic blood penetration seen	Pass. Test material resistant to synthetic blood penetration.
Synthetic blood penetration at seams and non-continuous components	ASTM F1670	Evaluate the resistance of test material at seams to penetration by synthetic blood under conditions of continuous liquid contact.	Pass determination based on no visual detection of synthetic blood penetration.	Material seams: no synthetic blood penetration seen	Pass. Test material seams resistant to synthetic blood penetration.
Viral Penetration	ASTM F1671	Evaluate the barrier performance of test material which are intended to protect against blood borne pathogen hazards.	Pass determination based on no visual detection of viral penetration and assay titer value <1˚	Visual penetration: none seen Assay Titer (PFU/mL): <1˚	Pass. Test material successfully protects against blood borne pathogen hazards.
Viral Penetration at seams and non-continuous components	ASTM F1671	Evaluate the barrier performance of test material at seams which are intended to protect against blood borne pathogen hazards.	Pass determination based on no visual detection of viral penetration and assay titer value <1˚	Visual penetration: none seen Assay Titer (PFU/mL): <1˚	Pass. Test material seam successfully protects against blood borne pathogen hazards.
Thickness	ASTM D6988-13	Determine the thickness of test material.	N/A	0.018mm	Thickness: 0.018mm

Clinical Performance Data

No needed for this device.

VIII. CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the Plasdent Disposable Barrier Sleeves and Barrier Films device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, the Pac-Dent Barrier Sleeve cleared under K151123, Class II (21 CFR 878.4370), product code PEM.