



Food and Drug Administration
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June 20, 2017

Premium Plus International Limited
Jessica Mao
QA Engineer
Flat 1001 Yuen Long Trading Centre, 33 Wang Yip Street West
Yuen Long N.t.
Hong Kong, CN

Re: K163447

Trade/Device Name: Premium Plus Disposable Barrier Sleeve
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape And Drape Accessories
Regulatory Class: Class II
Product Code: PEM
Dated: November 30, 2016
Received: December 8, 2016

Dear Jessica Mao:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Lori A. Wiggins -S6

Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K163447

Device Name

Premium Plus Disposable Barrier Sleeve

Indications for Use (Describe)

Premium Plus Disposable Barrier Sleeve is 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.

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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PREMIUM PLUS INTERNATIONAL LIMITED

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Section 5 510(k) Summary **[As Required by 21 CFR 807.92]**

510(k) Number: K163447

Submitter: Premium Plus International Limited
Flat 1001 Yuen Long Trading Centre,
No. 33 Wang Yip Street West,
Yuen Long, N.T. Hong Kong, China
(Establishment registration number: 3006847937)

Contact Person: Jessica Mao
QA Engineer
Tel: 852-27613211
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Trade Name: Premium Plus Disposable Barrier Sleeve
Common Name: Dental Barriers and Sleeves
Device Panel: General and Plastic Surgery
Basis for Submission: New Device
Regulation Name: Surgical Drape and Drape Accessories
Device Classification: Class II
Regulation Number: 21 CFR 878.4370
Product Code: PEM

Predicate Device to Premium Plus Disposable Barrier Sleeves:

Trade Name: Pac-Dent Barrier Sleeve
510(k) Number: K151123
Manufactured by: Pac-Dent International, Inc.

Device Description:

Premium Plus Disposable Barrier Sleeves are made of polyethylene film and are used as accessories to dental instruments and equipment used during dental procedures. These barrier sleeves consist of various sizes and shapes which are positioned on various small hand-held dental instruments such as handpieces, curing lights, air/water syringes and similar hand instruments. In other forms, they are used to cover various devices such as dental chairs, dental instrument trays, x-ray heads, and others. The products are sold non-sterile, prepackaged, and are disposable, single use only.

Indications for Use:

Premium Plus Disposable Barrier Sleeves 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.

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Device Models:

Model#	Description	Designed for
100A	Syringe Sleeves with Adhesive Tape, 500 pcs/box	3-way syringes, saliva ejectors and HVE valve
100B	Syringe Sleeves Blue, 500 pcs/box	3-way syringes, saliva ejectors and HVE valve
100C	Syringe Sleeves Clear, 500 pcs/box	3-way syringes, saliva ejectors and HVE valve
101	Tray Sleeves Standard 'B', 500 pcs/box	Instrument trays
102	Tray Sleeves Mini 'F', 500 pcs/box	Instrument trays
103	High Speed / Pen Sleeves, 500 pcs/box	Most handpieces, jet polishers and ultrasonic scalers
104	Low Speed / Universal Sleeves, 500 pcs/box	Most handpieces, jet polishers and ultrasonic scalers
105	Curing Light Handle Sleeves, 500 pcs/box	Curing light, pistol type
106	T Light Handle Sleeves, U-shape, 500 pcs/box	Most T-style dental chair light handles
107	Impression Gun Sleeves, 500 pcs/box	Impression guns
108	X-Ray Head / Keyboard Sleeves, 250 pcs/box	X-ray head/keyboard
109	X-Ray Head Sleeves Large, 250 pcs/box	X-ray head
111	Full Chair Sleeves, 125 pcs/box	Dental chairs
112	Half Chair / Stool Sleeves, 125 pcs/box	Dental chairs/stools
113	Headrest Sleeves Small, 500 pcs/box	Dental chair headrest
114	Headrest Sleeves Large, 500 pcs/box	Dental chair headrest
118	Straight Tubing Sleeves, 366 meters	Dental chair tubing
119	Coiled Tubing Sleeves, 366 meters	Dental chair tubing
123L	Curing Light Sleeves Pen Type Large, 500 pcs/box	Curing lights, pen type
123S	Curing Light Sleeves Pen Type Small, 500 pcs/box	Curing lights, pen type
123SS	Curing Light Sleeves Pen Type	Curing lights, pen type
	X-Small, 500 pcs/box	

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125	Intraoral Camera Sleeves, 500 pcs/box	Intraoral Cameras
125SS	Intraoral Camera/Curing Light Sleeves, 500 pcs/box	Intraoral Cameras/curing lights
128	Light Guide Sleeves, Small, 200 pcs/box	Curing light guides
129	Light Guide Sleeves, Large, 200 pcs/box	Curing light guides
133	PC Mouse Sleeves, 500 pcs/box	PC mice
135	HVE Suction Tube Sleeves, 500 pcs/box	HVE suction tubes
136	T Light Handle Sleeves, Rectangular, 500 pcs/box	T-style dental chair light handles
138	Flowable Composite Syringe Sleeves, 200 pcs/box	Composite syringes
140L	X-Ray Sensor Sleeves, Large, 500 pcs/box	X-ray sensors
140M	X-Ray Sensor Sleeves, Medium, 500 pcs/box	X-ray sensors
140S	X-Ray Sensor Sleeves, Small, 500 pcs/box	X-ray sensors
140XS	X-Ray Sensor/Mouth Mirror Sleeves, 500 pcs/box	X-ray sensors/mouth mirrors
145	Bite Block Sleeves, 1000 pcs/box	Bite Block
155	Tablet Sleeves, 500pcs/box	Tablet/Pad
158	Keyboard Sleeves, 500 pcs/box	Keyboards
183-1	X-Ray Sensor Sleeves Two Step, Size 1, 500	X-ray sensors
183-2	X-Ray Sensor Sleeves Two Step, Size 2, 500	X-ray sensors
190	ISO Tray Sleeves, 500 pcs/box	Instrument Trays
105T	Curing Light Sleeves Complete, 500 pcs/box	Curing lights
121	Lab Transport Bags, 100 pcs/box	Transport of dental materials
188-0	PSP X-Ray Barrier Envelopes, No. 0, 100 pcs/box	Phosphor Plates
188-1	PSP X-Ray Barrier Envelopes, No. 1, 100 pcs/box	Phosphor Plates
188-2	PSP X-Ray Barrier Envelopes, No. 2, 100 pcs/box	Phosphor Plates
188-2B	PSP X-Ray Barrier Envelopes, No. 2, 500 pcs/box	Phosphor Plates
188-3	PSP X-Ray Barrier Envelopes, No. 3, 50 pcs/box	Phosphor Plates
188-4	PSP X-Ray Barrier Envelopes, No. 4, 50 pcs/box	Phosphor Plates

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189-0	PSP X-Ray Barrier Envelopes, No. 0, 100 pcs/box	Phosphor Plates
189-1	PSP X-Ray Barrier Envelopes, No. 1, 100 pcs/box	Phosphor Plates
189-2	PSP X-Ray Barrier Envelopes, No. 2, 100 pcs/box	Phosphor Plates
198-0	PSP X-Ray Barrier Envelopes, No. 0, 100 pcs/box	Phosphor Plates
198-2	PSP X-Ray Barrier Envelopes, No. 2, 100 pcs/box	Phosphor Plates
198-2B	PSP X-Ray Barrier Envelopes, No. 2, 500 pcs/box	Phosphor Plates
199-0	PSP X-Ray Barrier Envelopes, No. 0, 100 pcs/box	Phosphor Plates
199-1	PSP X-Ray Barrier Envelopes, No. 1, 100 pcs/box	Phosphor Plates
199-2	PSP X-Ray Barrier Envelopes, No. 2, 100 pcs/box	Phosphor Plates
8008-B	Barrier Film 4" x 6", Clear, 1200 sheets/roll	Surface area that might be touched during procedure
8008-C	Barrier Film 4" x 6", Blue, 1200 sheets/roll	Surface area that might be touched during procedure

Overall Dimensions (by Inches):

Model#	Device Description	Size
100A	Syringe Sleeves with Adhesive Tape, 500 pcs/box	10 15/64"x2 9/16"
100B	Syringe Sleeves Blue, 500 pcs/box	10 15/64"x2 9/16"
100C	Syringe Sleeves Clear, 500 pcs/box	10 15/64"x2 9/16"
101	Tray Sleeves Standard 'B', 500 pcs/box	14 11/64"x10 5/8"
102	Tray Sleeves Mini 'F', 500 pcs/box	11 1/32"x7 31/64"
103	High Speed / Pen Sleeves, 500 pcs/box	8 21/32"x15/16"
104	Low Speed / Universal Sleeves, 500	8 21/31"x1 1/2"
105	Curing Light Handle Sleeves, 500 pcs/box	10 19/32"x5 19/32"
106	T Light Handle Sleeves, U-shape, 500 pcs/box	5 29/32"x3 11/32"
107	Impression Gun Sleeves, 500 pcs/box	8 17/64"x9 27/32"
108	X-Ray Head / Keyboard Sleeves, 250 pcs/box	23 5/8"x7 7/8"
109	X-Ray Head Sleeves Large, 250 pcs/box	29 17/32"x13 25/32"
111	Full Chair Sleeves, 125 pcs/box	70 55/64"x28 11/32"
112	Half Chair / Stool Sleeves, 125 pcs/box	39 3/8"x25 19/32"
113	Headrest Sleeves Small, 500 pcs/box	10 15/64"x10 53/64"
114	Headrest Sleeves Large, 500 pcs/box	11 1/32"x13 25/32"
118	Straight Tubing Sleeves, 366 meters	11 13/16"x1 31/32"
119	Coiled Tubing Sleeves, 366 meters	11 13/16"x3 15/16"

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123L	Curing Light Sleeves Pen Type Large, 500 pcs/box	13 25/32"x2 9/16"
123S	Curing Light Sleeves Pen Type Small, 500 pcs/box	12 19/32"x1 31/32"
123SS	Curing Light Sleeves Pen Type X-Small, 500 pcs/box	11 1/32"x1 31/32"
125	Intraoral Camera Sleeves, 500 pcs/box	12 19/32"x1 57/64"
125SS	Intraoral Camera/Curing Light Sleeves, 500 pcs/box	11 1/32"x1 57/64"
128	Light Guide Sleeves, Small, 200 pcs/box	3 15/32"x3 11/32"
129	Light Guide Sleeves, Large, 200 pcs/box	3 15/16"x3 35/64"
133	PC Mouse Sleeves, 500 pcs/box	5 29/32"x3 11/32"
135	HVE Suction Tube Sleeves, 500 pcs/box	2 11/64"x13 25/32"
136	T Light Handle Sleeves, Rectangular, 500 pcs/box	5 29/32"x3 15/16"
138	Flowable Composite Syringe Sleeves, 200 pcs/box	4 59/64"x1 31/32"
140L	X-Ray Sensor Sleeves, Large, 500 pcs/box	9 27/32"x2 23/64"
140M	X-Ray Sensor Sleeves, Medium, 500 pcs/box	7 7/8"x1 49/64"
140S	X-Ray Sensor Sleeves, Small, 500 pcs/box	7 7/8"x1 21/32"
140XS	X-Ray Sensor/Mouth Mirror Sleeves, 500 pcs/box	7 7/8"x1 1/2"
145	Bite Block Sleeves, 1000 pcs/box	2 11/64"x1 1/32"
155	Tablet Sleeves, 500pcs/box	7 7/8"x11 39/64"
158	Keyboard Sleeves, 500 pcs/box	6 19/64"x21 21/32"
183-1	X-Ray Sensor Sleeves Two Step, Size 1, 500	8 21/32"x1 31/32"
183-2	X-Ray Sensor Sleeves Two Step, Size 2, 500	8 21/32"x2 11/64"
190	ISO Tray Sleeves, 500 pcs/box	12 3/16"x8 1/4"
105T	Curing Light Sleeves Complete, 500 pcs/box	10 19/32"x5 19/32"
121	Lab Transport Bags, 100 pcs/box	8 21/32"x7 3/32"
188-0	PSP X-Ray Barrier Envelopes, No. 0, 100 pcs/box	1 27/64"x1 49/64"
188-1	PSP X-Ray Barrier Envelopes, No. 1, 100 pcs/box	1 31/32"x1 29/64"
188-2	PSP X-Ray Barrier Envelopes, No. 2, 100 pcs/box	2 1/64"x1 11/16"
188-2B	PSP X-Ray Barrier Envelopes, No. 2, 500 pcs/box	2 1/64"x1 11/16"
188-3	PSP X-Ray Barrier Envelopes, No. 3, 50 pcs/box	2 33/64"x1 1/2"
188-4	PSP X-Ray Barrier Envelopes, No. 4, 50 pcs/box	3 15/32"x2 43/64"
189-0	PSP X-Ray Barrier Envelopes, No. 0, 100 pcs/box	1 1/2"x1 3/8"
189-1	PSP X-Ray Barrier Envelopes, No. 1, 100 pcs/box	1 3/16"x2 3/32"
189-2	PSP X-Ray Barrier Envelopes, No. 2, 100 pcs/box	2 3/32"x1 29/64"
198-0	PSP X-Ray Barrier Envelopes, No. 0, 100 pcs/box	1 57/64"x1 7/32"
198-2	PSP X-Ray Barrier Envelopes, No. 2, 100 pcs/box	2 1/8"x1 1/2"
198-2B	PSP X-Ray Barrier Envelopes, No. 2, 500 pcs/box	2 1/8"x1 1/2"
199-0	PSP X-Ray Barrier Envelopes, No. 0, 100 pcs/box	1 47/64"x1 3/8"
199-1	PSP X-Ray Barrier Envelopes, No. 1, 100 pcs/box	2 3/64"x1 29/64"
199-2	PSP X-Ray Barrier Envelopes, No. 2, 100 pcs/box	2 1/8"x1 47/64"

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8008-B	Barrier Film 4" x 6", Clear, 1200 sheets/roll	4"x6"
8008-C	Barrier Film 4" x 6", Blue, 1200 sheets/roll	4"x6"

Comparison of Technological Characteristics and Performance:

Device	Pac-Dent Barrier Sleeve 510(K) Number: K151123	Premium Plus Disposable Barrier Sleeves
Intended Use	To be used as a barrier to cover dental instruments	To be used as a barrier for dental instruments and equipment
Classification Product Code	PEM	PEM
Material	Polyethylene film	Polyethylene film
Material Composition	Low density polyethylene and linear low density polyethylene film	Low density polyethylene and linear low density polyethylene film
Biocompatibility	Non-cytotoxic Non-sensitizing Non-irritating	Non-cytotoxic Non-sensitizing Non-irritating
Film Thickness	0.02mm- 0.06mm	0.03mm
Mechanical Properties(Pac-Dent 101 B Tray Sleeve was tested for comparison with the proposed device)	Tensile Strength – tested in compliance with ASTM D882 Puncture Resistance - tested in compliance with ASTM F1342 Tear Resistance - tested in compliance with ASTM D1424	Mechanical properties of the subject device are comparable to the predicate device. Tensile Strength, puncture resistance and tear resistance are equivalent to the predicate device.
Sterility	Non-sterile	Non-sterile
Single Use	Single use device	Single use device
Performance Properties	Synthetic Blood Penetration- Pass Viral Penetration-Pass	Synthetic Blood Penetration- Pass Viral Penetration-Pass
Dimensions	Determined by the size and shape of dental instruments and equipment	Difference in dimensions is due to the size of instruments and equipment they cover
FDA- Recognized Standards	ASTM F1670 ASTM F1671 ASTM D882 ASTM F1342 ASTM D1004 ISO 10993-5 ISO 10993-10	ASTM F1670 ASTM F1671 ASTM D882 ASTM F1342 ASTM D1004 ISO 10993-5 ISO 10993-10

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Tests:

Performance test including resistance to penetration, tear strength, tensile properties, resistance to puncture was performed. Biocompatibility test in accordance with ISO 10993-5, ISO 10993-10 has been performed. Effectiveness of x-ray devices covered with Premium Plus Disposable Barrier Sleeves was performed to demonstrate the subject device does not impact the function of dental x-ray devices.

The biocompatibility test result indicates that the disposable barrier sleeves do not have the potential cytotoxicity, hypersensitivity and irritation.

Clinical Performance Data:

No data from human clinical studies have been included to support the substantial equivalence of the proposed devices, Premium Plus International Limited, as clinical studies is not required for this medical device.

Conclusion

Based on the tests performed the subject device Premium Plus Disposable Barrier Sleeve is as safe and as effective, and performs as well as the legally marketed predicate device.