May 11, 2022

Premium Plus (Dongguan) Limited
Jessica Mao
Regulatory Affairs
No.1 Industrial Area, Tutang, Changping
Dongguan, Guangdong 523581
CHINA

Re: K220662
Trade/Device Name: Disposable Barrier Sleeves
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape And Drape Accessories
Regulatory Class: Class II
Product Code: PEM
Dated: March 2, 2022
Received: March 7, 2022

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. 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,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K220662

Device Name
Disposable Barrier Sleeves

Indications for Use *(Describe)*
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.

Model#	Description	Designed for
100B	Syringe/HVE Sleeves Blue	3-way syringes, saliva ejectors and HVE valve
100C	Syringe/HVE Sleeves Clear	3-way syringes, saliva ejectors and HVE valve
101	Tray Sleeves Standard 'B'	Instrument trays
102	Tray Sleeves Mini 'F'	Instrument trays
103	Pen Shaped Instrument Sleeves	Most handpieces, jet polishers and ultrasonic scalers
104L	Low Speed/ Universal Handpiece Sleeves, Large	Most handpieces, jet polishers and ultrasonic scalers
104S	Low Speed/ Universal Handpiece Sleeves, Small	Most handpieces, jet polishers and ultrasonic scalers
105T	Pistol Type Curing Light Sleeves	Curing light, pistol type
106	T-Style Light Handle Sleeves, U-shape	Most T-style dental chair light handles
107	Impression Gun Sleeves	Impression guns
108	X-Ray Head / Keyboard Sleeves	X-ray head/keyboard
109	X-Ray Head Sleeves	X-ray head
111	Full Chair Sleeves	Dental chairs
112	Half Chair Sleeves	Dental chairs/stools
113	Headrest Sleeves Small	Dental chair headrest
114	Headrest Sleeves Large	Dental chair headrest
118	Straight Tubing Sleeves	Dental chair tubing
119	Coiled Tubing Sleeves	Dental chair tubing
123L	Pen Type Curing Light Sleeves, Large	Curing lights, pen type
123S	Pen Type Curing Light Sleeves, Small	Curing lights, pen type
123SS	Pen Type Curing Light Sleeves, X-Small	Curing lights, pen type
123XL	Pen Type Curing Light Sleeves, X-Large	Curing lights, pen type
125	Intraoral Camera Sleeves	Intraoral Cameras
125SS	Intraoral Camera/RA Curing Light Sleeves	Intraoral Cameras/curing lights
128	Light Guide Sleeves, Small	Curing light guides
129	Light Guide Sleeves, Large	Curing light guides
133	PC Mouse Sleeves	PC mouses
135L	HVE Tube Sleeves, Large	HVE suction tubes
135S	HVE Tube Sleeves, Small	HVE suction tubes
136 T	Light Handle Sleeves, Rectangular	T-style dental chair light handles
138	Flowable Composite Syringe Sleeves	Composite syringes
140L	X-Ray Sensor Sleeves, Large	X-ray sensors
140M	X-Ray Sensor Sleeves, Medium	X-ray sensors
140S	X-Ray Sensor Sleeves	X-ray sensors
140XS	X-Ray Sensor/Mouth Mirror Sleeves	X-ray sensors/mouth mirrors
145	Bite Block Sleeves	Bite Block
158	Keyboard Sleeves	Keyboards
183-1	Two Step X-Ray Sensor Sleeves, Size 1	X-ray sensors
183-2	Two Step X-Ray Sensor Sleeves, Size 2	X-ray sensors

190	ISO Tray Sleeves	Instrument Trays
228	Intraoral Camera Sleeves/ RA Curing Light Sleeves Mini Short	Intraoral Camera, RA curing lights
8008-B	Barrier Film, Clear	Surface area that might be touched during procedure
8008-C	Barrier Film, Blue	Surface area that might be touched during procedure
188-0 PSP	X-Ray Barrier Envelopes, No. 0	Phosphor Plates
188-1 PSP	X-Ray Barrier Envelopes, No. 1	Phosphor Plates
188-2 PSP	X-Ray Barrier Envelopes, No. 2	Phosphor Plates
188-3 PSP	X-Ray Barrier Envelopes, No. 3	Phosphor Plates
188-4 PSP	X-Ray Barrier Envelopes, No. 4	Phosphor Plates
189-0 PSP	X-Ray Barrier Envelopes, No. 0	Phosphor Plates
189-1 PSP	X-Ray Barrier Envelopes, No. 1	Phosphor Plates
189-2 PSP	X-Ray Barrier Envelopes, No. 2	Phosphor Plates
198-0 PSP	X-Ray Barrier Envelopes, No. 0	Phosphor Plates
198-1 PSP	X-Ray Barrier Envelopes, No. 1	Phosphor Plates
198-2 PSP	X-Ray Barrier Envelopes, No. 2	Phosphor Plates
199-0 PSP	X-Ray Barrier Envelopes, No. 0	Phosphor Plates
199-1 PSP	X-Ray Barrier Envelopes, No. 1	Phosphor Plates
199-2 PSP	X-Ray Barrier Envelopes, No. 2	Phosphor Plates
8008-B	Barrier Film, Clear	Surface area that might be touched during procedure
8008-C	Barrier Film, Blue	Surface area that might be touched during procedure

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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