May 9, 2024

Yongqing Huaguan Dental Instruments Factory
℅ Jarvis Wu
Senior Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Building, 1500# Century Ave
Shanghai, Shanghai 200122
CHINA

Re: K233918
Trade/Device Name: Dental Barrier and Sleeves
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape And Drape Accessories
Regulatory Class: Class II
Product Code: PEM
Dated: April 10, 2024
Received: April 10, 2024

Dear Jarvis Wu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Michael Adjodha, MChE, RAC, CQIA
Assistant Director
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OHT1: Office of Ophthalmic, Anesthesia,
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233918

Device Name

Dental Barrier and Sleeves

Indications for Use *(Describe)*

Dental Barrier and 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.

See the attached table for the model numbers and descriptions in 510(k) Summary.

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

K233918

Document prepared date: 2024/04/10

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B. Device:

Trade Name: Dental Barrier and Sleeves
Common Name: Dental Barrier and Sleeves

Regulatory Information
Classification Name: Surgical Drape And Drape Accessories
Classification: Class II
Product code: PEM
Regulation Number: 21 CFR 878.4370

C. Predicate device:

Predicate Device: K190484
Product name: BH Medical Dental Barrier Sleeves and Barrier Film
Manufacturer: BH Medical Products Co., Ltd.

D. Intended use of the device:

Dental Barrier and 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

E. Device Description:

Dental Barrier and Sleeves consist of various sizes and shapes of polyethylene covers which are positioned on various small hand-held dental instruments such as hand pieces, 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.

Table for the model numbers and descriptions :

Item	Model#	Model Description	Designed for
Models for intra-orally use (Subject to this 510k submission)			
1	HL-6562/ HL-6563	Air/Water Syringe Sleeves	Air/Water Syringe, HVE Universal 2-1/2 " ×10 "
2	HL-6564	Month Mirror Covers or Sleeves	Dental Mirror 1-1/2 " ×8 "
3	HL-6565	Low Speed Handpiece Sleeves	Dental Low-Speed Handpiece Universal 1-1/2 " ×8 "
4	HL-6566	High Speed Handpiece Sleeves	Dental High-Speed Handpiece Universal 1 " ×8 "
5	HL-6577	X-Ray Covers	X-Ray Universal 15 " ×26 "
6	HL-6578	3 - function sprayer Sleeves	3-Fuction Sprayer 7-3/10 " ×5 "
7	HL-6579	Scaler Covers	Dental Scaler 1-3/5 " ×8 "
8	HL-6580	Intraoral Camera Sheath	Intraoral Camera 9-4/5 " ×2 "
9	HL-6581	Digital X-ray Sensor Covers	Digital X-Ray Sensor, Universal 2-1/2 " ×10 "
10	HL-6582-1	Digital X-ray Sensor Covers	Digital X-Ray Sensor, Universal 8 " ×1-5/8 "
11	HL-6582-2	Digital X-ray Sensor Covers	Digital X-Ray Sensor, Universal 8 " ×1-3/8 "
12	HL-6585	Syringe Sleeves (Roll bag)	Syringe 2.2 " ×17.7 "
13	HL-6586	Turbine Motor Sleeves (Roll bag)	Turbine 1.8 " ×17.7 "
14	HL-6588S	Curing Light Sleeves	Dental Curing Light 4.33"X2.95"
15	HL-6588L	Curing Light Sleeves	Dental Curing Light 4.33"X2.95"
16	HL-6597	Curing Light Sleeves	Dental Curing Light 4.7” ×1.2”
17	HL-6592	Curing Light Sleeves	Dental Curing Light 13 " ×2.1 "
18	HL-6593	Curing Light Sleeves	Dental Curing Light 13 " ×3.3 "
19	HL-6594	Intraoral Camera Sleeve	Intraoral Camera 10.2 " ×2 "
20	HL-6595	Curing Light Sleeves	Dental Curing Light 9.9"X1.85"
21	HL-6596	Curing Light Sleeves	Dental Curing Light 12.4"X4.13"
22	HL-6604	Disposable Barrier Sleeves	Barrier Sleeve 9.25 " ×3.15 "
23	HL-6605	Disposable Barrier Sleeves	Barrier Sleeve 11.2 " ×2.2 "
24	HL-6606	Disposable Barrier Sleeves	Barrier Sleeve 11.2 " ×2.2 "

25	HL-6607	Low Speed Handpiece Cover	Low Speed Handpiece 7.5 " ×1.53 "
26	HL-6608	X-ray sensors Cover	X-Ray Sensor 8 " ×1-5/8 "
27	HL-6610	Digital Sensor Envelopes	Dightal Sensor 2"X4.5"
28	HL-6611	Digital Sensor Envelopes	Dightal Sensor 1-5/8"X4"
29	HL-6612	Digital Sensor Envelopes	Dightal Sensor 1.6"X4.5"
30	HL-6613	Digital Sensor Envelopes	Dightal Sensor 1.4"X4.3"
31	HL-6614	Bite Block Covers	Bite Block 1.4"X2.5"
32	HL-6615	Intraoral Camera Sleeve	Intraoral Camera 35mm*110mm
33	HL-6579S	Scaler Covers	Dental Scaler 1.4 " ×7 "
34	HL-6701	Fitted Digital Sensor Sleeves	Digital Sensor 2″ ×9.124″
35	HL-20963	Intraoral Camera Sheath	Intraoral Camera 220mm*48mm
36	HL-21013	Intraoral Camera Sheath	Intraoral Camera 210*57mm
37	HL-20855	Intraoral Camera Sheath	Intraoral Camera 228mm*57mm
38	HL-20999	X-ray Sensor Sheath	Digital X-Ray Sensor(Dexis) Compatible TIDI:20999 225mm*57mm
39	HL-20978	X-ray Sensor Sheath	Digital X-Ray Sensor(Kodak 6100 Size 1)Compatible TIDI:20978 226mm*57mm
40	HL-20824	X-ray Sensor Sheath	For SCHICK Size 1 Compatible TIDI:20824 220mm*47mm
41	HL-20861	X-ray Sensor Sheath	Digital Sensor 223mm*57mm
42	HL-20825	X-ray Sensor Sheath	For SCHICK Size 2 Compatible TIDI:20825 220mm*57mm
43	HL-20979	X-ray Sensor Sheath	Digital X-Ray Sensor(Kodak 6100 Size 2) 223mm*56mm
44	HL-20831	Intraoral Camera Sheath	Intraoral Camera 225mm*55mm
45	HL-6577A	X-ray Barrier	X-Ray 23" X 31 "
46	HL-6577B	X-ray Barrier	X-Ray 14" X 13" X 24.5"
47	HL-100	Barrier Film	Surface Area That Might Be Touched During Procedure 4"X6"
48	HL-101	Barrier Film Blue	Surface Area That Might Be Touched During Procedure 4"X6"
49	HL- A Size 0	X-ray Barrier Envelopes	Phosphor Plates Size 0 Inner: 22×35mm
50	HL- A Size 1	X-ray Barrier Envelopes	Phosphor Plates Size 1 Inner:24mmx40mm
51	HL- A Size 2	X-ray Barrier Envelopes	Phosphor Plates Size Inner:31mmx41mm
52	HL- A Size 3	X-ray Barrier Envelopes	Phosphor Plates Size 3 Inner: 27mmx54mm
53	HL- A Size 4	X-ray Barrier Envelopes	Phosphor Plates Size 4 Inner: 57mmx76mm
54	HL- B Size 0	X-ray Barrier Envelopes	Phosphor Plates Size 0 Inner: 22×35mm
55	HL- B Size 1	X-ray Barrier Envelopes	Phosphor Plates Size 1 Inner:24mmx40mm

56	HL- B Size 2	X-ray Barrier Envelopes	Phosphor Plates Size Inner:31mmx41mm
57	HL- B Size 3	X-Ray Barrier Envelopes	Phosphor Plates Size 3 Inner: 27mmx54mm
58	HL- B Size 4	X-Ray Barrier Envelopes	Phosphor Plates Size 4 Inner: 57mmx76mm
59	IC-001	Intraoral Camera Sleeves	Intraoral Camera 1'' HEAD X 2'' OPENING X 8.25'' LENGTH
60	IC-085	Intraoral Camera Sleeves	Intraoral Camera 0.85'' HEAD X 1.75'' OPENING X 8.25'' LENGTH
61	PS-00/01	Digital Sensor Cover	Dental Sensor 9"L * 1-3/4"W
62	PS-002	Comfort Sensor Sleeves	Dental Sensor 9"L*2"W
63	PS-5500	Perforated Bite Block Covers	Bite Block 1"W * 2"L
64	PS-5501	Perforated Bite Block Covers	Bite Block 1 1/2"W X 3"L
65	PS-5502	Large Digital Sensor Covers	Digital Sensor 2-3/4"W * 8"L
66	PS-5505	Universal Digital Sensor Covers	Digital Sensor 1-1/2"W *7"L
67	PS-5511	Large Comfort Sensor Covers	Dental Sensor 2"W *4-1/2"L
68	PS-5522	Comfort Sensor Covers, #2	Dental Sensor 1-5/8"W * 4-1/8"L
69	PS-5533	Comfort Sensor Covers, #0/#1	Dental Sensor 1-3/8"W * 4-1/4"L
70	PS-CYGNUS-1	Digital Sensor Sleeves Cygnus#1	Digital Dental Sensor 24*3.5
71	PS-DEXIS-U	Digital Sensor Sleeves Dexis Universal	Digital Dental Sensor 9.5"*1.77"
72	PS308	Air/Water Syringe Cover	Air Water Syringe 2 ½'' X 8 ¼''
73	PS321	Air/Water Syringe Cover (¾'' Seal)	Air Water Syringe 2 ½'' X10''
74	PS3767-WO	Air/Water Syringe Cover (Notched)	Air Water Syringe 2 ½'' X10"
75	PS4500	Curing Light Tip Sleeves	Curing Light FOR 7-8mm TIP STICK HOLD
76	PS4511	Curing Light Tip Sleeves	Curing Light FOR 11mm TIP STICK HOLD
77	PS4700	Cordless Curing Light Cover	Curing Light 1 ¾'' X 9 ¾''
78	PS4701	Cordless Curing Light Cover	Curing Light 2" X 12 ¾''
79	PS4707	Cordless Curing Light Cover	Curing Light 4" X 12 ½''
80	PS4708	Cordless Curing Light Cover	Curing Light 3 ¼'' X 13"
81	PS730	Scaler Sleeves-Stick Hold	Dental Scaler Stick Hold 1-1/2"W*7"L
82	PS735	Scaler Sleeves	Dental Scaler 1-⅝'' X 8"
83	XS-6100-0	Digital Sensor Sheath For Kodak Size 0	Digital Sensor 24*3.5
84	XS-6100-1	Digital Sensor Sheath For Kodak Size 1	Digital Sensor 24*4.3
85	XS-6100-2	Digital Sensor Sheath For Kodak Size 2	Digital Sensor 24*4.3

86	XS-CYGNUS-1	Digital Sensor Sheath For Cygnus Size 1	Digital Sensor 24*3.5
87	XS-DEXIS-2	Digital Sensor Sheath For Dexis Size 2	Digital Sensor 24*3.9
88	XS-DEXIS-U	Digital Sensor Sheath For Dexis Universal	Digital Sensor
89	XS-GXDR-1	Digital Sensor Sheath For Gendex/Xdr Size 1	Digital Sensor 24*3.4
90	XS-GXDR-2	Digital Sensor Sheath For Gendex/Xdr Size 2	Digital Sensor 24*3.9
91	XS-SHICK-1	Digital Sensor Sheath For Schick Size 1	Digital Sensor 24*3.5
92	XS-SHICK-2	Digital Sensor Sheath For Schick Size 2	Digital Sensor 24*4.3
93	SS100	Single Syringe Sleeves	Single Syringe 210mm*51mm*0.0275
94	SS200	Automix Syringe Sleeves	Automix Syringe 235mm*65mm*0.0275
Models for non intra-orally use			
95	HL-6567	T Light Handle Covers	Light Handle For T-Style 4 " L×5-3/4 " W
96	HL-6568	Tray Sleeves	Dental Instrument Tray 11-5/8 " ×16 "
97	HL-6569	Tray Sleeves	Dental Instrument Tray 10-1/2 " ×14 "
98	HL-6569S	Tray Sleeves	Dental Instrument Tray 7 1/2 " ×10 1/2 "
99	HL-6571	Headrest Covers	Dental Chair Headrest 11"X10"
100	HL-6572	Headrest Covers	Dental Chair Headrest 14"X10"
101	HL-6573-1	Half Chair Covers	Half Dental Chair 27-1/2 " ×24 "
102	HL-6573-2	Half Chair Covers	Half Dental Chair 32 " ×32 "
103	HL-6574/ HL-6576	Full Chair Covers	Full Dental Chair 29 " ×80 "
104	HL-6575	Full Chair Covers	Wide Full Dental Chair 48 " ×56 "
105	HL-6583	T Light Handle Covers	Light Handle Cover 6 " ×2-9/10 "
106	HL-6587	Headrest Covers (Roll bag)	Dental Chair Headrest 11.8 " ×9 "
107	HL-6601	PC mouse Covers	PC Mouse 6.25 " ×3.5 "
108	HL-6702	Keyboard Covers	Keyboard 22"X13.78"
109	HL-6568-2	Tray Barriers	Dental Instrument Tray 11-5/8" X 14" Size A
110	HL-6569-2	Tray Barriers	Dental Instrument Tray 11.5" X 16" Size E
111	HL-7510	Tray Barriers	Dental Instrument Tray 7.5" X 10.5" Size F
112	HL-7521	Keyboard Cover	Keyboard 22" X 14"
113	PS101	Small Half Chair Cover	Dental Chair 20’’W X 30’’L
114	PS105	Full Chair Cover	Dental Chair 33’’W X 54’’L
115	PS203	Size E Tray Cover W/Lock Top	Plastice/Metal Trays 11-1/2"*16"
116	PS328T	T-Shape Lite Handle Cover	T-Shape Lite Handle 6"W X 3"L

117	PS408	Wireless Keyboard Covers	Keyboard 24"Lx 10"W
118	PS410-STWD	Wide Lcd Cover	Monitor And Keyboard 25"WX16"L W/3" POCKET
119	PS410-WD	Wide Lcd+Keyboard Cover	Monitor And Keyboard 25"W*26"Lw/3"POCKET
120	PS670	Chair Armrest Covers	Chair Armrest 24"Lx6"W
121	PS680	Jumbo Headrest Cover	Chair Headrest 14 1/2"L X 14 3/4"W

F. Comparison with predicate device

Device	Subject Device	Predicate Device	Comment
Manufacturer	Yongqing Huaguan Dental Instruments Factory	BH Medical Products Co., Ltd..	/
510K number	K233918	K190484	/
Product Name	Dental Barrier and Sleeves	BH Medical Dental Barrier Sleeves and Barrier Film	/
Classification	Class II Device (21 CFR 878.4370)	Class II Device (21 CFR 878.4370)	Same
Intended use	Dental Barrier and 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	BH Medical Dental 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.	Same
Device Description	Dental Barrier and Sleeves consist of various sizes and shapes of polyethylene covers which are positioned on various small hand-held dental instruments such as hand pieces, 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.	BH Medical Dental Barrier Sleeves and Barrier Film consist of various sizes and shapes of clear polyethylene covers which are positioned on various small hand-held dental instruments such as hand pieces, 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.	Same
Classification Product Code	PEM	PEM	
Material	Polyethylene film	Polyethylene film	Same
Material Composition	LLDPE(80%),LDPE(20%)	LLDPE(80%),LDPE(20%),Blue pigment(#992482),Adhesive(#992482,#992483)	Same
Specifications and Tolerances	Paper Backing: Some of the model; Film Thickness: 0.02-0.06mm Tolerance:<0.01mm	Paper Backing: No Film Thickness: 0.025mm Tolerance:<0.01mm	Similar
Labeling	Single use device	Single use device	Same

Sterility	Non-sterile	Non-sterile	Same
Performance Properties	Synthetic Blood Penetration test (ASTM F1670) -Pass Viral Penetration test (ASTM F1671)-Pass	Synthetic Blood Penetration test (ASTM F1670) -Pass Viral Penetration test (ASTM F1671)-Pass	Same
Biocompatibility	Biocompatibility tests were conducted in compliance with ISO 10993-5, ISO 10993-10 and ISO 10993-23 Test results indicate the device is non-cytotoxic, non-sensitizing and non-irritating.	Biocompatibility tests were conducted in compliance with ISO 10993-5 and ISO 10993-10. Test results indicate the device is non-cytotoxic, non-sensitizing and non-irritating.	Same
Dimensions	Difference in dimensions is due to the size of instruments and equipment they cover	Difference in dimensions is due to the size of instruments and equipment they cover	Same
FDA-Recognized Standards	ASTM F1670 ASTM F1671 ASTM D882 ASTM F1342 ASTM D1004 ISO 10993-5 ISO 10993-10 ISO 10993-23	ASTM F1670 ASTM F1671 ASTM D882 ASTM F1342 ASTM D1004 ISO 10993-5 ISO 10993-10	Same

Substantial Equivalence Discussion:

The subject and predicate devices have the same intended use. Both are single-use devices, and material and performance characteristic are identical. The minor differences in specifications and tolerances between the subject and predicate devices do not raise questions of safety and effectiveness.

G. Non-Clinical Testing

Performance test including resistance to penetration, tear resistance, tensile strength, puncture resistance was performed. Biocompatibility test in accordance with ISO 10993-5, ISO 10993-10 and ISO 10993-23 has been performed. Effectiveness of x-ray devices covered with Dental Barrier and Sleeves were performed to demonstrate the subject device does not impact the function of dental x-ray devices.

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

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

Based on the comparison and analysis above, the subject device, Dental Barrier and Sleeves, is as safe, as effective, and performs as well as or better than the legally marketed predicate devices.