



September 10, 2019

BH Medical Products Co., Ltd.
Xiaohua Tao
President
No.90 Shenjiang Villagers' group,
Zhangjiacunwei, Xilin Street,
Zhonglou District
Changzhou, 213024 Cn

Re: K190484

Trade/Device Name: BH Medical Dental 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: August 6, 2019
Received: August 12, 2019

Dear Xiaohua Tao:

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 Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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

Indications for Use

510(k) Number (if known)

K190484

Device Name

BH Medical Dental Barrier Sleeves and Barrier Film

Indications for Use (Describe)

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.

Item #	Model	Designed for
#992514	B tray sleeves	Dental instrument tray, 10 1/2"x14"(360x270mm)
#992515	E tray sleeves	Dental instrument tray, 11 1/2"x16"(410x290mm)
#992516	A tray sleeves	Dental instrument tray, 7 1/2"x10 1/2"(270x190mm)
#992446	Headrest Cover	Dental chair headrest, 11"x9 1/2"(250x280mm)
#992447	Headrest Cover	Dental chair headrest, 14"x9 1/2"(250x360mm)
#992513	X-ray head sleeves	X-ray head, universal, 15"x26"(660x380mm)
#992481	Full chair sleeves	Dental chair, universal, 29"x80"(2020x730mm)
#992479	Half chair sleeves	Half dental chair, universal, 27 1/2"x24"(680x600mm)
#992486	Syringe/HVE sleeve without tape	Air/water syringe HVE universal, 2 1/2"x10"(250x60x22mm)
#991372	Digital x-ray sensor sleeve	Digital x-ray sensor, universal, large, 1 5/8"x8"(210x43mm)
#991371	Digital x-ray sensor sleeve	Digital x-ray sensor, universal, large, 1 3/8"x8"(210x36mm)
#992492	handpiece and pen sleeves-High speed	Dental high-speed handpiece universal(200x28mm)
#992493	handpiece and pen sleeves-Lower speed	Dental low-speed handpiece universal(200x38mm)
#992499	light handle sleeves	light handles, universal, T-shape(154x73mm)
#992508	light handle sleeves	light handles, universal, Rectangular(150x105mm)
#992495	light cure sleeves	Dental curing light, medium,20mm
#992496	light cure sleeves	Dental curing light, large,25mm
#992497	light cure sleeves, curved tip	Dental curing light, medium,(340x53x16mm)
#992498	light cure sleeves, curved tip	Dental curing light, large,(340x84x16mm)
#992582	light cure sleeves, pen style	Dental curing light, pen type,tip:40x27mm,total:250x50mm
#992583	light cure sleeves, pen style	Dental curing light, pen type,,tip:55x26mm,total:250x52mm
#992584	light cure sleeves, pen style	Dental curing light, pen type,tip:40x30mm,total:250x55mm
#991361	Barrier envelopes size 0	Digital x-ray sensor(Kodak 6100 size 0) ,inner :36x23mm
#991362	Barrier envelopes size 1	Digital x-ray sensor(Kodak 6100 size 1) ,inner :42x26mm
#991363	Barrier envelopes size 2	Digital x-ray sensor(Kodak 6100 size 2) ,inner :45x33mm
#991364	Barrier envelopes size 3	Digital x-ray sensor(Kodak 6100 size 3) ,inner :56x30mm
#991365	Barrier envelopes size 4	Digital x-ray sensor(Kodak 6100 size 4) ,inner :80x60mm
#992489	Tubing sleeves roll (2")	Dental unit tubing, 2", (50mm)
#992490	Tubing sleeves roll (4")	Dental unit tubing, 4", (100mm)
#992483	Barrier film white	Surface area that might be touched during procedure 4"x6", white, 10cmx15cmx180m
#992482	Barrier film blue	Surface area that might be touched during procedure 4"x6", blue, 10cmx15cmx180m
#992585	Intraoral Camera Sleeves	Digital intraoral camera sleeves, DMD Telicam, 228x43x13.5mm
#992586	Intraoral Camera Sleeves	Digital intraoral camera sleeves, Siemens Ceracam/minicam Ultra, 228x43x24mm
#992587	Intraoral Camera Sleeves	Digital intraoral camera sleeves, Dentsply Acucap

		Concept, 228x43x16.6mm
#992588	Intraoral Camera Sleeves	Digital intraoral camera sleeves, Camsight OptumII, 228x25x17mm
#992589	Intraoral Camera Sleeves	Digital intraoral camera sleeves, RF System SS21, 228x57x22mm
#992590	Intraoral Camera Sleeves	Digital intraoral camera sleeves, Suni Sunic-am,228x48x31mm
#992591	Intraoral Camera Sleeves	Digital intraoral camera sleeves, Digital Doc Iris,228x41x19mm
#992592	Intraoral Camera Sleeves	Digital intraoral camera sleeves, Vision Tools Spectra Vu, 228x57x12mm
#992593	Intraoral Camera Sleeves	Digital intraoral camera sleeves, Imagin Hot Rod, 228x50x17.5mm
#992594	Intraoral Camera Sleeves	Digital intraoral camera sleeves, Carestream STV Pro I&II Kodak 1000, 228x35x18mm
#992595	Intraoral Camera Sleeves	Digital intraoral camera sleeves, Video Dental Concepts Miniscope & Microscope TD-2000,228x53x29mm
#992596	Intraoral Camera Sleeves	Digital intraoral camera sleeves, DMD Telicam Digital Doc Aurara, 228x35x22mm
#991367	Barrier envelopes size 0	Digital x-ray sensor (size 0),inner :25x37mm
#991368	Barrier envelopes size 1	Digital x-ray sensor (size 1),inner :26.5x43mm
#991369	Barrier envelopes size 2	Digital x-ray sensor (size 2),inner :44x33mm
#991374	Sensor sleeves	Dental instrument tray, 100x43mm
#991373	Sensor sleeves	Dental instrument tray, 250x63mm

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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Section 5 510(k) Summary

[As Required by 21 CFR 807.92]

Submitter: BH Medical Products Co., Ltd.
No.90 Shenjiang Villagers' group, Zhangjiacunwei, Xilin Street,
Zhonglou District, Changzhou City, Jiangsu Province,
People's Republic of China
(Establishment registration number: 3009307523)

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UNITED STATES
Contact Person: Bryan Shields
Tel: (916) 718-0795
Email: bshields@ismiledp.com

Device/Trade Name: BH Medical Dental Barrier Sleeves and Barrier Film
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 BH Medical Dental Barrier Sleeves and Barrier Film:

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

Device Description:

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.

Indications for Use:

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.

Table for the product names and model numbers:

Item	Model	Description	Designed for
1	#992514	B tray sleeves	Dental instrument tray, 10 1/2"x14"(360x270mm)
2	#992515	E tray sleeves	Dental instrument tray, 11 1/2"x16"(410x290mm)
3	#992516	A tray sleeves	Dental instrument tray, 7 1/2"x10 1/2"(270x190mm)
4	#992446	Headrest Cover	Dental chair headrest, 11"x9 1/2"(250x280mm)
5	#992447	Headrest Cover	Dental chair headrest, 14"x9 1/2"(250x360mm)
6	#992513	X-ray head sleeves	X-ray head, universal, 15"x26"(660x380mm)
7	#992481	Full chair sleeves	Dental chair, universal, 29"x80"(2020x730mm)
8	#992479	Half chair sleeves	Half dental chair, universal, 27 1/2"x24"(680x600mm)
9	#992486	Syringe/HVE sleeve without tape	Air/water syringe HVE universal, 2 1/2"x10"(250x60x22mm)
10	#991372	Digital x-ray sensor sleeve	Digital x-ray sensor, universal, large, 1 5/8"x8"(210x43mm)
11	#991371	Digital x-ray sensor sleeve	Digital x-ray sensor, universal, large, 1 3/8"x8"(210x36mm)
12	#992492	handpiece and pen sleeves-High speed	Dental high-speed handpiece universal(200x28mm)
13	#992493	handpiece and pen sleeves-Lower speed	Dental low-speed handpiece universal(200x38mm)
14	#992499	light handle sleeves	light handles, universal, T-shape(154x73mm)
15	#992508	light handle sleeves	light handles, universal, Rectangular(150x105mm)
16	#992495	light cure sleeves	Dental curing light, medium,20mm
17	#992496	light cure sleeves	Dental curing light, large,25mm
18	#992497	light cure sleeves, curved tip	Dental curing light, medium,(340x53x16mm)
19	#992498	light cure sleeves, curved tip	Dental curing light, large,(340x84x16mm)
20	#992582	light cure sleeves, pen style	Dental curing light, pen type,tip:40x27mm,total:250x50mm

21	#992583	light cure sleeves, pen style	Dental curing light, pen type,,tip:55x26mm,total:250x52mm
22	#992584	light cure sleeves, pen style	Dental curing light, pen type,tip:40x30mm,total:250x55mm
23	#991361	Barrier envelopes size 0	Digital x-ray sensor(Kodak 6100 size 0) ,inner :36x23mm
24	#991362	Barrier envelopes size 1	Digital x-ray sensor(Kodak 6100 size 1) ,inner :42x26mm
25	#991363	Barrier envelopes size 2	Digital x-ray sensor(Kodak 6100 size 2) ,inner :45x33mm
26	#991364	Barrier envelopes size 3	Digital x-ray sensor(Kodak 6100 size 3) ,inner :56x30mm
27	#991365	Barrier envelopes size 4	Digital x-ray sensor(Kodak 6100 size 4) ,inner :80x60mm
28	#992489	Tubing sleeves roll (2“)	Dental unit tubing, 2”,(50mm)
29	#992490	Tubing sleeves roll (4“)	Dental unit tubing, 4”,(100mm)
30	#992483	Barrier film white	Surface area that might be touched during procedure 4"x6",white,10cmx15cmx180m
31	#992482	Barrier film blue	Surface area that might be touched during procedure 4"x6",blue,10cmx15cmx180m
32	#992585	Intraoral Camera Sleeves	Digital intraoral camera sleeves, DMD Telicam,228x43x13.5mm
33	#992586	Intraoral Camera Sleeves	Digital intraoral camera sleeves, Siemens Ceracam/minicam Ultra,228x43x24mm
34	#992587	Intraoral Camera Sleeves	Digital intraoral camera sleeves, Dentsply Acucap Concept,228x43x16.6mm
35	#992588	Intraoral Camera Sleeves	Digital intraoral camera sleeves, Camsight OptumII,228x25x17mm
36	#992589	Intraoral Camera Sleeves	Digital intraoral camera sleeves, RF System SS21,228x57x22mm
37	#992590	Intraoral Camera Sleeves	Digital intraoral camera sleeves, Suni Sunic-am,228x48x31mm
38	#992591	Intraoral Camera Sleeves	Digital intraoral camera sleeves, Digital Doc Iris,228x41x19mm

39	#992592	Intraoral Camera Sleeves	Digital intraoral camera sleeves, Vision Tools Spectra Vu,228x57x12mm
40	#992593	Intraoral Camera Sleeves	Digital intraoral camera sleeves, Imagin Hot Rod,228x50x17.5mm
41	#992594	Intraoral Camera Sleeves	Digital intraoral camera sleeves, Carestream STV Pro I&II Kodak 1000,228x35x18mm
42	#992595	Intraoral Camera Sleeves	Digital intraoral camera sleeves, Video Dental Concepts Miniscope & Microscope TD-2000,228x53x29mm
43	#992596	Intraoral Camera Sleeves	Digital intraoral camera sleeves, DMD Telicam Digital Doc Aurara,228x35x22mm
44	#991367	Barrier envelopes size 0	Digital x-ray sensor (size 0),inner :25x37mm
45	#991368	Barrier envelopes size 1	Digital x-ray sensor (size 1),inner :26.5x43mm
46	#991369	Barrier envelopes size 2	Digital x-ray sensor (size 2),inner :44x33mm
47	#991374	Sensor sleeves	Dental instrument tray, 100x43mm
48	#991373	Sensor sleeves	Dental instrument tray, 250x63mm

Comparison of Technological Characteristics:

Item	Predicate Device	Subject Device	Comment
Device	Pac-Dent Barrier Sleeve 510(K) Number: K151123	BH Medical Dental Barrier Sleeves and Barrier Film	/
Indications for Use	Pac-Dent Barrier Sleeve are intended to be used as a barrier to cover dental instruments. It is non-sterile and is 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	Pac-Dent Barrier Sleeves consist of various sizes and shapes of clear polyethylene covers 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,	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	Same

	dental instrument trays, x-ray heads, and others.	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.	
Classification Product Code	PEM	PEM	Same
Material	Polyethylene film	Polyethylene film	Same
Material Composition	LLDPE(80%),LDPE(20%),Blue pigment(Item#100B,C101B),Adhesive(Item#C101,C101B)	LLDPE(80%),LDPE(20%),Blue pigment(#992482),Adhesive(#992482,#992483)	Same
Specifications and Tolerances	Paper backing: some of 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	Non-cytotoxic Non-sensitizing 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	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	Same
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	Same

Tests:

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 has been performed. Effectiveness of x-ray devices covered with BH Dental 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 barrier sleeves do not have the potential cytotoxicity, sensitization and irritation.

Clinical Performance Data:

NA

Conclusion

Based on the tests performed the subject device BH Medical Dental Barrier Sleeves and Barrier Film is as safe, as effective, and performs as well as or better than the legally marketed predicate device.