DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 3, 2016

Pac-Dent International, Inc.
Wenying Zhu
Materials Engineer
670 Endeavor Circle
Brea, CA 92821

Re: K151123
Trade/Device Name: Pac-Dent Barrier Sleeve, Cover-It™ Barrier Film
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: PEM
Dated: February 1, 2016
Received: February 4, 2016

Dear Ms. Zhu:

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 yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151123

Device Name
Pac-Dent Barrier Sleeve, Cover-It(TM) Barrier Film

Indications for Use *(Describe)*
Pac-Dent Barrier Sleeve and Cover-It Barrier Film are intended to be used as a barrier to cover dental instruments. This device is non-sterile and is intended for single patient use only.

Item#	Model	Designed for
101	B tray sleeves	Dental instrument tray (size B)
101A	A tray sleeves	Dental instrument tray (size A)
102	Headrest cover	Dental chair headrest, 11"X9 1/2"
103	Headrest cover	Dental chair headrest, jumbo, 14"X9 1/2"
104	F tray sleeves	Dental instrument tray (size F)
109	X-Ray sleeves	X-Ray head, universal, 15"X26"
110	Universal X-Ray sleeves	X-Ray head, universal, extra-long, 23"X31"
111	Full chair sleeves	Dental chair, universal, 29"X80"
111SG	S&G full chair sleeves	Dental chair, Slip and Grip, 48"X56"
112	Half chair sleeves	Half dental chair, universal, 27 1/2"X24"
100	Syringe sleeve w. opening, clear	Air/water syringe HVE, universal
100B	Syringe sleeve w. opening, blue	Air/water syringe HVE, universal
100L	Digital sensor sleeve	Digital X-Ray sensor, universal, large, 1 5/8"X8"
100S	Digital sensor sleeve	Digital X-Ray sensor, universal, small, 1 3/8"X8"
103HP	High-speed handpiece sleeves	Dental high-speed handpiece, universal
104HP	Low-speed handpiece sleeves	Dental low-speed handpiece, universal
106	“T” handle sleeves	T-style light handles, universal
190LED	Sleeves for L.E. Demetron	Dental curing light (L.E. Demetron)
D250	LED Curing light sleeves for Demi	Dental curing light (Demi)
S121	Keyboard sleeves	Computer keyboard, universal, 22"X14"
S122	Keyboard sleeves	Computer keyboard, large, 19"X26"
S123	LCD & Keyboard sleeves	Computer screen and keyboard, universal
S124	Laptop sleeves	Laptop, universal
LCH500	Low-speed contra-angle handpiece sleeves w/paper backing	Dental low-speed contra-angle handpiece, universal
LLH500	Low-speed long handpiece sleeves w/paper backing	Dental low-speed long handpiece, universal
CM500	Optical PC mouse barriers	Computer mouse, universal
AWP400	Syringe sleeve W/paper backing	Air/water syringe, universal
DX-405	X-ray sensor sheaths, Gender,XDR® Size 1	Digital X-Ray sensor (Gender,XDR® Size 1)
DX-406	X-ray sensor sheaths, Gender,XDR® Size 2	Digital X-Ray sensor (Gender,XDR® Size 2)
DX-819	X-ray sensor sheaths, Suni/Lightyear	Digital X-Ray sensor (Suni/Lightyear)
DX-824	X-ray sensor sheaths, Schick/Dr.Suni Plus	Digital X-Ray sensor (Schick/Dr.Suni Plus)
DX-825	X-ray sensor sheaths, Schick/Dr.Suni Plus	Digital X-Ray sensor (Schick/Dr.Suni Plus)
DX-890	X-ray sensor sheaths, Sirona Size 2	Digital X-Ray sensor (Sirona Size 2)
DX-904	X-ray sensor sheaths, Sirona Size 1	Digital X-Ray sensor (Sirona Size 1)
DX-977	X-ray sensor sheaths, Kodak 6100 Size 0	Digital X-Ray sensor (Kodak 6100 Size 0)
DX-978	X-ray sensor sheaths, Kodak 6100 Size 1	Digital X-Ray sensor (Kodak 6100 Size 1)
DX-979	X-ray sensor sheaths, Kodak 6100 Size 2	Digital X-Ray sensor (Kodak 6100 Size 2)
DX-999	X-ray sensor sheaths, Dexis	Digital X-Ray sensor (Dexis)

PIC250	Complete iCure curing light sleeves	Dental curing light (iCure)
CS250	Complete curing light sleeves	Dental curing light, universal
P3720	Tube sleeves(2”)	Dental unit tubing (2”)
P3740	Tube sleeves(4”)	Dental unit tubing (4”)
P4550	Curing Light Handle Sleeves	Curing light handle, universal
C101	Cover It Barrier film, clear	Surface area that might be touched during procedure, 4"X6"
C101B	Cover It Barrier film, blue	Surface area that might be touched during procedure, 4"X6"

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 IV

510(k) Summary

Submitter:
Pac-Dent International, Inc.
670 Endeavor Circle
Brea, CA 92821
Contact Person:
Wenying Zhu
Materials Engineer
909-839-0888 ext.111
Date Summary Prepared:
02/15/2016

Device Name

Trade Name: Pac-Dent Barrier Sleeve, Cover-It™ Barrier Film
Common Name: Dental Barriers and Sleeves
Device Classification: Class II
Classification Product Code: PEM
Classification Name: Surgical drape and drape accessories per 21 CFR 878.4370

Predicate Device

Primary predicate device: TiDiShield Curing Light Sleeve - K132953
Reference Device: Cover-All, Chair Sleeve, Drape-it-All, Tray Sleeve, related products - K962288

Description of Device

Pac-Dent Barrier Sleeve and Cover-It™ Barrier Film 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, dental instrument trays, x-ray heads, and others. The products are sold non-sterile, prepackaged, and are disposable, single use only.

Indications for Use

Pac-Dent Barrier Sleeve and Cover-It™ Barrier Film are intended to be used as a barrier to cover dental instruments. This device is non-sterile and is intended for single patient use only.

Item#	Model	Designed for
101	B tray sleeves	Dental instrument tray (size B)

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101A	A tray sleeves	Dental instrument tray (size A)
102	Headrest cover	Dental chair headrest, 11"X9 1/2"
103	Headrest cover	Dental chair headrest, jumbo, 14"X9 1/2"
104	F tray sleeves	Dental instrument tray (size F)
109	X-Ray sleeves	X-Ray head, universal, 15"X26"
110	Universal X-Ray sleeves	X-Ray head, universal, extra-long, 23"X31"
111	Full chair sleeves	Dental chair, universal, 29"X80"
111SG	S&G full chair sleeves	Dental chair, Slip and Grip, 48"X56"
112	Half chair sleeves	Half dental chair, universal, 27 1/2"X24"
100	Syringe sleeve w. opening, clear	Air/water syringe HVE, universal
100B	Syringe sleeve w. opening, blue	Air/water syringe HVE, universal
100L	Digital sensor sleeve	Digital X-Ray sensor, universal, large, 1 5/8"X8"
100S	Digital sensor sleeve	Digital X-Ray sensor, universal, small, 1 3/8"X8"
103HP	High-speed handpiece sleeves	Dental high-speed handpiece, universal
104HP	Low-speed handpiece sleeves	Dental low-speed handpiece, universal
106	“T” handle sleeves	T-style light handles, universal
190LED	Sleeves for L.E. Demetron	Dental curing light (L.E. Demetron)
D250	LED Curing light sleeves for Demi	Dental curing light (Demi)
S121	Keyboard sleeves	Computer keyboard, universal, 22"X14"
S122	Keyboard sleeves	Computer keyboard, large, 19"X26"
S123	LCD & Keyboard sleeves	Computer screen and keyboard, universal
S124	Laptop sleeves	Laptop, universal
LCH500	Low-speed contra-angle handpiece sleeves w/paper backing	Dental low-speed contra-angle handpiece, universal
LLH500	Low-speed long handpiece sleeves w/paper backing	Dental low-speed long handpiece, universal
CM500	Optical PC mouse barriers	Computer mouse, universal
AWP400	Syringe sleeve W/paper backing	Air/water syringe, universal
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DX-819	X-ray sensor sheaths, Suni/Lightyear	Digital X-Ray sensor (Suni/Lightyear)
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DX-825	X-ray sensor sheaths, Schick/Dr.Suni Plus	Digital X-Ray sensor (Schick/Dr.Suni Plus)
DX-890	X-ray sensor sheaths, Sirona Size 2	Digital X-Ray sensor (Sirona Size 2)
DX-904	X-ray sensor sheaths, Sirona Size 1	Digital X-Ray sensor (Sirona Size 1)

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DX-977	X-ray sensor sheaths, Kodak 6100 Size 0	Digital X-Ray sensor (Kodak 6100 Size 0)
DX-978	X-ray sensor sheaths, Kodak 6100 Size 1	Digital X-Ray sensor (Kodak 6100 Size 1)
DX-979	X-ray sensor sheaths, Kodak 6100 Size 2	Digital X-Ray sensor (Kodak 6100 Size 2)
DX-999	X-ray sensor sheaths, Dexis	Digital X-Ray sensor (Dexis)
PIC250	Complete iCure curing light sleeves	Dental curing light (iCure)
CS250	Complete curing light sleeves	Dental curing light, universal
P3720	Tube sleeves(2”)	Dental unit tubing (2”)
P3740	Tube sleeves(4”)	Dental unit tubing (4”)
P4550	Curing Light Handle Sleeves	Curing light handle, universal
C101	Cover It™ Barrier film, clear	Surface area that might be touched during procedure, 4"X6"
C101B	Cover It™ Barrier film, blue	Surface area that might be touched during procedure, 4"X6"

Comparison of Technological Characteristics and Performance

Descriptive Information	**Subject Device** Pac-Dent Barrier Sleeve, Cover-It™ Barrier Film	**Primary Predicate Device** TiDiShield Curing Light Sleeve (K132953)	**Reference Device** Cover-All (K962288)
Indications for Use	To be used as a barrier to cover dental instruments.	Use as a barrier that is used as an accessory to dental instrument.	To act as a physical barrier, augmenting existing infection control techniques and make clean-up and disinfection easier.
Classification Product Code	PEM	PEM	MMP
Composition of Materials	LLDPE (80%) LDPE (20%) Blue pigment (item#100B, C101B) Adhesive (item#C101, C101B)	LLDPE (80%) LDPE (20%)	LLDPE (80%) LDPE (20%)
Specifications and Tolerances	Paper backing: some of the model Film thickness: 0.02-0.06mm Tolerance: <0.01mm	Paper backing: Yes Film thickness: 0.02mm Tolerance: <0.01mm	Paper backing: some of the model Film thickness: 0.02-0.06mm Tolerance: <0.01mm
Sterility	Non-sterile	Non-sterile	Non-sterile
Labeling	Single Use Only	Single Use Only	Single Use Only
Performance	· Film Thickness	· Film Thickness	· Film Thickness

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Testing	· Resistance to Penetration - ASTM F1670: pass - ASTM F1671: pass · Tear Strength - ASTM D1424: subject device is equivalent to the predicate device · Tensile Properties - ASTM D882: subject device is equivalent to the predicate device · Resistance to Puncture - ASTM F1342: subject device is equivalent to the predicate device · Biocompatibility - ISO10993-5 in vitro cytotoxicity Under the conditions of the study, the subject device was non-cytotoxic. - ISO 10993-10 irritation Under the conditions of the study, the subject device was not an irritant - ISO 10993-10 sensitization Under the conditions of the study, the subject device was not a sensitizer · Effectiveness of X-Ray Devices Covered with Barrier Sleeves	· Synthetic Blood Resistance - ASTM F1670 · Tear Strength - ASTM D1424 · Tensile Properties - ASTM D882 · Resistance to Puncture - ASTM F1342	· Synthetic Blood Resistance - ASTM F1670 · Tear Strength - ASTM D1424 · Tensile Properties - ASTM D882 · Resistance to Puncture - ASTM F1342
FDA-Recognized Standards	ANSI/AAMI PB70:2012 ASTM F1670 ASTM D1004 ASTM D882 ASTM F1342 ASTM F1671 ISO 10993-5 ISO 10993-10	ANSI/AAMI PB70:2012 ASTM F1670 ASTM D1004 ASTM D882 ASTM F1342	ANSI/AAMI PB70:2012 ASTM F1670 ASTM D1004 ASTM D882 ASTM F1342

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The product code PEM (Dental Barriers and Sleeves) better describes the subject device than MMP (Cover, Barrier, Protective). Therefore, the subject device uses PEM as its product code.

Non-Clinical Tests

Performance test including resistance to penetration, tear strength, tensile properties, resistance to puncture was performed in comparison to the predicate device. Effectiveness of X-Ray Devices Covered with Barrier Sleeves was performed to demonstrate the subject device does not impact the function of dental x-ray devices.
Biocompatibility test in accordance with ISO10993-5, ISO10993-10 has been performed.

Clinical Performance Test

No clinical testing was provided.

Summary of Non-Clinical and Clinical Performance Testing

The performance test result shows that the subject device performs as well as the predicate devices.
The biocompatibility test result shows that the subject device was found to be not an irritant or a sensitizer and non –cytotoxic under the conditions of the studies.

Conclusion

The performance data support the conclusion that the subject device is as safe and as effective and performs as well as the legally marketed devices identified TiDiShield Curing Light Sleeve (K132953) and Cover-All, Chair Sleeve, Drape-it-All, Tray Sleeve, related products (K962288).