



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

June 7, 2016

DENTSPLY International
Ms. Helen Lewis
Director Corporate Regulatory Affairs
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K160232

Trade/Device Name: Disposable Barrier Sleeves and Covers
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: PEM
Dated: May 6, 2016
Received: May 9, 2016

Dear Ms. Lewis:

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,

A handwritten signature in black ink that reads "Susan Russo, DDS, MA". The signature is written in a cursive style. In the background, there is a faint, semi-transparent watermark of the FDA logo.

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

Indications for Use

510(k) Number (if known)
K160232

Device Name
Disposable Barriers Sleeves and Covers

Indications for Use (Describe)

Disposable Barrier Sleeves and Covers are intended to serve 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 product names, trade names and model numbers.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

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Disposa-Shield® Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only.

Models:

Part Number (SKU)	Description	Designed For
A88005	Disposable Barrier for Low Speed, Contra-Angle Handpiece	Low Speed, Contra-Angle Handpieces Fits Cavitron Handpiece
65090003	DISPOSA-SHIELD® No. 3 Air Turbines and Cavitron, A88005	Low Speed, Contra-Angle Handpieces Fits Cavitron Handpiece
A88006	Disposable Barrier for Low Speed, Long Handpiece	Low Speed, Long Handpieces Fits: SmartLite PS, Tulsa 6:1, ContraAngle Handpiece by Sirona, e ³ Torque Control Motor, MIDWEST Handpiece
A88007	Disposable Barrier for Universal Air/Water Syringe	Universal Air/Water Syringe (syringe type delivery system)
65090002	DISPOSA-SHIELD® No. 2 Air Motors, A88007	Universal Air/Water Syringe (syringe type delivery system)
A88008	Disposable Barrier for Light Handle (T-Bar)	Light Handle (T-Bar)
A88013	Disposable Barrier for Standard Type Delivery Systems	Syringe Type Delivery Systems Fits Delton FS+ Syringe
A880095	Disposable Barrier for Dental Hose	Dental Hose
A880105	Disposable Barrier for Universal Chair/X-Ray Head	Universal Chair / X-Ray Head
A880115	Disposable Barrier for Multi-Purpose Use	Multi-Purpose Use
65090001	DISPOSA-SHIELD® No. 1 Light Handles and Control Panels, A880115	Multi-Purpose Use
A88014	Disposable Barrier for Tray Size 10 1/2" x 14 1/2"	Tray Size 10-1/2" x 14-1/2"
A88015	Disposable Barrier for Tray Size 12" x 17"	Tray Size 12" x 17"
A88016	Disposable Barrier for Dental Chair Head Rest	Dental Chair Head Rest
65090004	DISPOSA-SHIELD® No. 4 Headrest Cover, A88016	Dental Chair Head Rest
A88018	Disposable Barrier for Midwest RDH Freedom Inner Module	Midwest RDH Freedom Inner Module
A88019	Disposable Barrier for Midwest RDH Freedom with SmartMode Technology Inner Module	Midwest RDH Freedom Cordless Proply System with SmartMode Technology

Part Number (SKU)	Description	Designed For
737007	Disposable Barrier for Standard Type Delivery Systems, Trial Pack for A88013	Syringe Type Delivery Systems Fits Delton FS+ Syringe
90736	Disposable Barrier for Midwest RDH Freedom Inner Module, Trial Pack for A88018	Midwest RDH Freedom Inner Module
978079	Bebop Barrier Sleeve	Impression Material Dispenser

RINN® Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only.

Models:

Part Number (SKU)	Description	Designed For
050500	Universal Digital Sensor Covers (Bulk)	RINN® Digital Sensor Covers, Size 1 and Size 2
550500	Universal Digital Sensor Covers	RINN® Digital Sensor Covers, Size 1 and Size 2
550200	Large Sensor Cover (Soft Overbag Cover)	RINN® Large Digital Sensors Sized to overbag sensor and sensor holder (such as Snap-A-Ray DS)
550143	Tight Digital Sensor Cover – Size 1.5/2, 300-pack	Digital Sensors, size 1.5/2 Fits the following size 1.5 and 2 sensors: Schick CDR, Schick 33, Dexis, Kodak 6100, Gendex eHd, Gendex GXS-700
055574	Tight Digital Sensor Cover – Size 1.5/2, 25-pack	Digital Sensors, size 1.5/2 Fits the following size 1.5 and 2 sensors: Schick CDR, Schick 33, Dexis, Kodak 6100, Gendex eHd, Gendex GXS-700
055629	Tight Digital Sensor Cover - Size 1.5/2	Digital Sensors, size 1.5/2 Fits the following size 1.5 and 2 sensors: Schick CDR, Schick 33, Dexis, Kodak 6100, Gendex eHd, Gendex GXS-700
550149	Tight Sensor Cover – Size 1, 300-pack	Digital Sensors, size 1 Fits the following size 1 sensors: Planmeca, Instrumentarium, Schick, Gendex, Kodak, Dentex

Part Number (SKU)	Description	Designed For
055575	Tight Digital Sensor Cover - Size 1, 25-pack	Digital Sensors, size 1 Fits the following size 1 sensors: Planmeca, Instrumentarium, Schick, Gendex, Kodak, Dentex
055630	Tight Sensor Covers – Size 1	Digital Sensors, size 1 Fits the following size 1 sensors: Planmeca, Instrumentarium, Schick, Gendex, Kodak, Dentex
<p>Sani-Shield® and Sani-Tip® Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only. Models: 120126, 130010 and 1300105 Disposable Barrier for Air/Water Syringes air designed for Sani-Tip air/water syringe tips.</p>		
<p>Smartlite® Max Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only. Model: 644060 SmartLite® Max Disposable Barrier Sleeves is designed for SmartLite® Max L.E.D Curing Light. 644.50.030 SmartLite Focus Sleeve Refill is designed for Caulk K-156 SL Focus, SL PS.</p>		
<p>Endo® Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only. Model: EAPB100 (EAS100) EndoActivator Protective Barrier is designed for EAD100 EndoActivator Handpiece/Driver.</p>		
<p>digit® power Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only. Model: 678079 digit® power Disposable Barrier Sleeves Refill is designed for Aquasil Ultra cordless Tissue Managing Impression System and Fits digit® power Dispenser.</p>		

SECTION 5. 510(k) SUMMARY
for
Disposable Barrier Sleeves and Covers

1. Submitter Information:

Dentsply Sirona
221 West Philadelphia Street
Suite 60
York, PA 17404

Contact Person: Helen Lewis
Telephone Number: 717-487-1332
Fax Number: 717-849-4343

Date Prepared: 29 January 2016

2. Device Name:

- Proprietary Name: Disposable Barrier Sleeves and Covers
- Classification Name: Dental Barriers and Sleeves
- CFR Number: 878.4370
- Device Class: II
- Product Code: PEM

3. Predicate Device:

Predicate Device Name	510(k)	Company Name
TIDIShield™ Curing Light Sleeve	K132953	TIDI Products, LLC

4. Description of Device:

The proposed devices, Disposable Barrier Sleeves and Covers, are made of polyethylene film and are used as accessories to dental instruments and equipment used during dental procedures. These disposable barrier sleeves and covers are offered in various shapes and sizes to fit over and cover the intended dental instruments and equipment. The Disposable Barrier Sleeves slip over the ends of the respective devices, allowing for the attachment and/or protrusion (where applicable) of those parts of the devices used during dental procedures. The Disposable Barrier Cover is placed over equipment, such as dental chair head rests and trays, to cover those parts.

The proposed devices, Disposable Barrier Sleeves and Covers, act as a physical barrier, augmenting existing infection control techniques, and facilitate clean-up.

5. Indications for Use:

Disposable Barrier Sleeves and Covers are intended to serve 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 product names, trade names and model numbers.

Disposa-Shield® Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only.

Models:

Part Number (SKU)	Description	Designed For
A88005	Disposable Barrier for Low Speed, Contra-Angle Handpiece	Low Speed, Contra-Angle Handpieces Fits Cavitron Handpiece
65090003	DISPOSA-SHIELD® No. 3 Air Turbines and Cavitron, A88005	Low Speed, Contra-Angle Handpieces Fits Cavitron Handpiece
A88006	Disposable Barrier for Low Speed, Long Handpiece	Low Speed, Long Handpieces Fits: SmartLite PS Tulsa 6:1, ContraAngle Handpiece by Sirona e ³ Torque Control Motor MIDWEST Handpiece
A88007	Disposable Barrier for Universal Air/Water Syringe	Universal Air/Water Syringe (syringe type delivery system)
65090002	DISPOSA-SHIELD® No. 2 Air Motors, A88007	Universal Air/Water Syringe (syringe type delivery system)
A88008	Disposable Barrier for Light Handle (T-Bar)	Light Handle (T-Bar)
A88013	Disposable Barrier for Standard Type Delivery Systems	Syringe Type Delivery Systems Fits Delton FS+ Syringe
A880095	Disposable Barrier for Dental Hose	Dental Hose
A880105	Disposable Barrier for Universal Chair/X-Ray Head	Universal Chair / X-Ray Head
A880115	Disposable Barrier for Multi-Purpose Use	Multi-Purpose Use
65090001	DISPOSA-SHIELD® No. 1 Light Handles and Control Panels, A880115	Multi-Purpose Use
A88014	Disposable Barrier for Tray Size 10 ½" x 14 ½"	Tray Size 10-1/2" x 14-1/2"

Part Number (SKU)	Description	Designed For
A88015	Disposable Barrier for Tray Size 12" x 17"	Tray Size 12" x 17"
A88016	Disposable Barrier for Dental Chair Head Rest	Dental Chair Head Rest
65090004	DISPOSA-SHIELD® No. 4 Headrest Cover, A88016	Dental Chair Head Rest
A88018	Disposable Barrier for Midwest RDH Freedom Inner Module	Midwest RDH Freedom Inner Module
A88019	Disposable Barrier for Midwest RDH Freedom with SmartMode Technology Inner Module	Midwest RDH Freedom Cordless Prophy System with SmartMode Technology Inner Module
737007	Disposable Barrier for Standard Syringe Type Delivery Systems, Trial Pack for A88013	Syringe Type Delivery Systems Fits Delton FS+ Syringe
90736	Disposable Barrier for Midwest RDH Freedom Inner Module, Trial Pack for A88018	Midwest RDH Freedom Inner Module
978079	Bebop Barrier Sleeve	Impression Material Dispenser

RINN® Universal Digital Sensor Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only.

Models:

Part Number (SKU)	Description	Designed For
050500	Universal Digital Sensor Covers (Bulk)	RINN® Digital Sensor Covers, Size 1 and Size 2
550500	Universal Digital Sensor Covers	RINN® Digital Sensor Covers, Size 1 and Size 2
550200	Large Sensor Cover (Soft Overbag Cover)	RINN® Large Digital Sensors Sized to overbag sensor and sensor holder (such as Snap-A-Ray DS)

Part Number (SKU)	Description	Designed For
550143	Tight Digital Sensor Cover – Size 1.5/2, 300-pack	Digital Sensors, size 1.5/2 Fits the following size 1.5 and 2 sensors: Schick CDR, Schick 33, Dexis, Kodak 6100, Gendex eHd, Gendex GXS-700
055574	Tight Digital Sensor Cover – Size 1.5/2, 25-pack	Digital Sensors, size 1.5/2 Fits the following size 1.5 and 2 sensors: Schick CDR, Schick 33, Dexis, Kodak 6100, Gendex eHd, Gendex GXS-700
055629	Tight Digital Sensor Cover - Size 1.5/ 2	Digital Sensors, size 1.5/2 Fits the following size 1.5 and 2 sensors: Schick CDR, Schick 33, Dexis, Kodak 6100, Gendex eHd, Gendex GXS-700
550149	Tight Sensor Cover – Size 1, 300-pack	Digital Sensors, size 1 Fits the following size 1 sensors: Planmeca, Instrumentarium, Schick, Gendex, Kodak, Dentex
055575	Tight Digital Sensor Cover - Size 1, 25-pack	Digital Sensors, size 1 Fits the following size 1 sensors: Planmeca, Instrumentarium, Schick, Gendex, Kodak, Dentex
055630	Tight Sensor Covers – Size 1	Digital Sensors, size 1 Fits the following size 1 sensors: Planmeca, Instrumentarium, Schick, Gendex, Kodak, Dentex

Sani-Shield® and Sani-Tip® Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only.

Models: 120126, 130010 and 1300105 Disposable Barrier for Air/Water Syringes air designed for Sani-Tip air/water syringe tips.

Smartlite® Max Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only.

Model:

644060 SmartLite® Max Disposable Barrier Sleeves is designed for SmartLite® Max L.E.D Curing Light.

644.050.030 SmartLite Focus Sleeve Refill is designed for Caulk K-156 SL Focus, SL PS.

Endo® Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only.

Model: EAPB100 (EAS100) EndoActivator Protective Barrier is designed for EAD100 EndoActivator Handpiece/Driver.

digit® power Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only.

Model: 678079 digit® power Disposable Barrier Sleeves Refill is designed for Aquasil Ultra cordless Tissue Managing Impression System and Fits digit® power Dispenser.

6. Substantial Equivalence:

Table 5.2 Technological Characteristics

<u>Element</u>	<u>Proposed Device</u> Disposable Barrier Sleeves and Covers	<u>Predicate Device</u> TIDIShield™ Curing Light Sleeve (K132953)
<u>510(k)</u>	<u>To be assigned</u>	<u>K132953</u>
Indications for Use	<p>Disposable Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only.</p> <p>See the attached table for the product names, trade names and model numbers.</p>	<p>TIDIShield™ Curing Light Sleeves are indicated for use as a barrier that is used as an accessory to dental instrument. These sleeves are non-sterile and are intended for single patient only.</p>

<u>Element</u>	<u>Proposed Device</u> Disposable Barrier Sleeves and Covers		<u>Predicate Device</u> TIDIShield™ Curing Light Sleeve (K132953)	
	Disposa-Shield® Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only. Models:			
	Part Number (SKU)	Description		Designed For
	A88005	Disposable Barrier for Low Speed, Contra-Angle Handpiece		Low Speed, Contra-Angle Handpieces Fits Cavitron Handpiece
	65090003	DISPOSA-SHIELD® No. 3 Air Turbines and Cavitron, A88005		Low Speed, Contra-Angle Handpieces Fits Cavitron Handpiece
	A88006	Disposable Barrier for Low Speed, Long Handpiece		Low Speed, Long Handpieces Fits: SmartLite PS, Tulsa 6:1, ContraAngle Handpiece by Sirona, e ³ Torque Control Motor, MIDWEST Handpiece
	A88007	Disposable Barrier for Universal Air/Water Syringe		Universal Air/Water Syringe (syringe type delivery system)
	65090002	DISPOSA-SHIELD® No. 2 Air Motors, A88007		Universal Air/Water Syringe (syringe type delivery system)
	A88008	Disposable Barrier for Light Handle (T-Bar)		Light Handle (T-Bar)
	A88013	Disposable Barrier for Standard Type Delivery Systems		Syringe Type Delivery Systems Fits Delton FS+ Syringe
	A880095	Disposable Barrier for Dental Hose		Dental Hose
	A880105	Disposable Barrier for Universal Chair/X-Ray Head		Universal Chair / X-Ray Head
	A880115	Disposable Barrier for Multi-Purpose Use		Multi-Purpose Use
	65090001	DISPOSA-SHIELD® No. 1 Light Handles and Control Panels, A880115		Multi-Purpose Use

<u>Element</u>	<u>Proposed Device</u> Disposable Barrier Sleeves and Covers			<u>Predicate Device</u> TIDIShield™ Curing Light Sleeve (K132953)
	Part Number (SKU)	Description	Designed For	
	A88014	Disposable Barrier for Tray Size 10 ½” x 14 ½”	Tray Size 10-1/2" x 14-1/2"	
	A88015	Disposable Barrier for Tray Size 12” x 17”	Tray Size 12" x 17"	
	A88016	Disposable Barrier for Dental Chair Head Rest	Dental Chair Head Rest	
	65090004	DISPOSA-SHIELD® No. 4 Headrest Cover, A88016	Dental Chair Head Rest	
	A88018	Disposable Barrier for Midwest RDH Freedom Inner Module	Midwest RDH Freedom Inner Module	
	A88019	Disposable Barrier for Midwest RDH Freedom with SmartMode Technology Inner Module	Midwest RDH Freedom Cordless Prophy System with SmartMode Technology	
	737007	Disposable Barrier for Standard Type Delivery Systems, Trial Pack for A88013	Syringe Type Delivery Systems Fits Delton FS+ Syringe	
	90736	Disposable Barrier for Midwest RDH Freedom Inner Module, Trial Pack for A88018	Midwest RDH Freedom Inner Module	
	978079	Bebop Barrier Sleeve	Impression Material Dispenser	
	<p>RINN® Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only.</p>			

<u>Element</u>	<u>Proposed Device</u> Disposable Barrier Sleeves and Covers			<u>Predicate Device</u> TIDIShield™ Curing Light Sleeve (K132953)	
	Models:				
	Part Number (SKU)	Description	Designed For		
	050500	Universal Digital Sensor Covers (Bulk)	RINN® Digital Sensor Covers, Size 1 and Size 2		
	550500	Universal Digital Sensor Covers	RINN® Digital Sensor Covers, Size 1 and Size 2		
	550200	Large Sensor Cover (Soft Overbag Cover)	RINN® Large Digital Sensors Sized to overbag sensor and sensor holder (such as Snap-A-Ray DS)		
	550143	Tight Digital Sensor Cover – Size 1.5/2, 300-pack	Digital Sensors, size 1.5/2 Fits the following size 1.5 and 2 sensors: Schick CDR, Schick 33, Dexis, Kodak 6100, Gendex eHd, Gendex GXS-700		
	055574	Tight Digital Sensor Cover – Size 1.5/2, 25-pack	Digital Sensors, size 1.5/2 Fits the following size 1.5 and 2 sensors: Schick CDR, Schick 33, Dexis, Kodak 6100, Gendex eHd, Gendex GXS-700		
	055629	Tight Digital Sensor Cover - Size 1.5/ 2	Digital Sensors, size 1.5/2 Fits the following size 1.5 and 2 sensors: Schick CDR, Schick 33, Dexis, Kodak 6100, Gendex eHd, Gendex GXS-700		
	550149	Tight Sensor Cover – Size 1, 300-pack	Digital Sensors, size 1 Fits the following size 1 sensors: Planmeca, Instrumentarium, Schick, Gendex, Kodak, Dentex		
	055575	Tight Digital Sensor Cover - Size 1, 25-pack	Digital Sensors, size 1 Fits the following size 1 sensors: Planmeca, Instrumentarium, Schick, Gendex, Kodak, Dentex		
055630	Tight Sensor Covers – Size 1	Digital Sensors, size 1 Fits the following size 1 sensors: Planmeca, Instrumentarium, Schick, Gendex, Kodak, Dentex			

<u>Element</u>	<u>Proposed Device</u> Disposable Barrier Sleeves and Covers	<u>Predicate Device</u> TIDIShield™ Curing Light Sleeve (K132953)
	<p>Sani-Shield® and Sani-Tip® Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only. Models: 120126, 130010 and 1300105 Disposable Barrier for Air/Water Syringes air designed for Sani-Tip air/water syringe tips.</p> <p>Smartlite® Max Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only. Model: 644060 SmartLite® Max Disposable Barrier Sleeves is designed for SmartLite® Max L.E.D Curing Light. 644.50.030 SmartLite Focus Sleeve Refill is designed for Caulk K-156 SL Focus, SL PS.</p> <p>Endo® Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only. Model: EAPB100 (EAS100) EndoActivator Protective Barrier is designed for EAD100 EndoActivator Handpiece/Driver.</p> <p>digit® power Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only. Model: 678079 digit® power Disposable Barrier Sleeves Refill is designed for Aquasil Ultra cordless Tissue Managing Impression System and Fits digit® power Dispenser.</p>	

<u>Element</u>	<u>Proposed Device</u> Disposable Barrier Sleeves and Covers	<u>Predicate Device</u> TIDIShield™ Curing Light Sleeve (K132953)
Material	Polyethylene film	Polyethylene film
Material Composition	Supplier #1 (PacDent): low density polyethylene and linear low density polyethylene film Supplier #2 (MiniTube AB): low density polyethylene film	Ethylene methyl acrylate copolymer and low density polyethylene film
Biocompatibility	Supplier #1 (PacDent): Non-cytotoxic Non-sensitizing Non-irritating Supplier #2 (MiniTube AB): Non-cytotoxic Non-sensitizing Non-irritating	Non-cytotoxic Non-sensitizing Non-irritating
Performance Properties	Synthetic Blood Penetration- Pass Synthetic Blood Penetration at seams and non-continuous components-Pass Viral Penetration- Pass Viral Penetration at seams and non-continuous components-Pass	Synthetic Blood Penetration-Pass Viral Penetration-Pass
Mechanical Properties	Tensile Strength <ul style="list-style-type: none"> • 0.02mm-Acceptable • 0.03mm-Acceptable • 0.05mm-Comparable to predicate Puncture Resistance <ul style="list-style-type: none"> • 0.02mm-Acceptable • 0.03mm-Acceptable • 0.05mm-Comparable to predicate Tear Resistance <ul style="list-style-type: none"> • 0.02mm-Acceptable • 0.03mm-Acceptable • 0.05mm-Comparable to predicate 	Tensile Strength <ul style="list-style-type: none"> • 0.05mm- Acceptable Puncture Resistance <ul style="list-style-type: none"> • 0.05mm- Acceptable Tear Resistance <ul style="list-style-type: none"> • 0.05mm- Acceptable

<u>Element</u>	<u>Proposed Device</u> Disposable Barrier Sleeves and Covers	<u>Predicate Device</u> TIDIShield™ Curing Light Sleeve (K132953)		
Thickness	PacDent: 0.02mm, 0.03mm, 0.05mm MiniTube AB: 0.03mm	0.05mm		
Shape	Custom design to fit the intended dental instruments and equipment they cover (Reference Table 5.3).	Custom design to fit the intended instrument.		
Dimensions	Determined by the size and shape of the dental instruments and equipment they cover (Reference Table 5.3).	Part #	Length (in)	Width (in)
		21103	10 1/8"	2 3/16"
		21102	10 1/8"	2 1/4"
		21101	10 1/8"	2 1/2"
		21100	10 1/8"	2 3/16"
		Difference in Dimensions is due to the difference in size of the instruments they cover.		
Color	Clear, except for RINN Tight Cover barrier sleeves RINN Tight Cover barrier sleeves are clear with white tabs and blue tabs. Part numbers 550143, 055574, 055629, 550149, 05575, and 055630.	Clear		
Sterile	Not sterile	Not sterile		
Single Use	Single use device	Single use device		

Table 5.3 Overall Dimensions (by Inches and Millimeters)

Part Number	Device Description	Size
A88005	Disposable Barrier for Low Speed, Contra-Angle Handpiece	4.91 in. x 8.90 in.
65090003	DISPOSA-SHIELD® No. 3 Air Turbines and Cavitron, A88005	4.91 in. x 8.90 in.
A88006	Disposable Barrier for Low Speed, Long Handpiece	1.56 in. x 7.60 in.
A88007	Disposable Barrier for Universal Air/Water Syringe	2.30 in. x 5.63 in.
65090002	DISPOSA-SHIELD® No. 2 Air Motors, A88007	2.30 in. x 5.63 in.
A88008	Disposable Barrier for Light Handle (T-Bar)	2.94 in. x 6.81 in.
A88013	Disposable Barrier for Standard Type Delivery Systems	1.37 in. x 7.60 in.
A880095	Disposable Barrier for Dental Hose	2.1 in. x 24.0 in.
A880105	Disposable Barrier for Universal Chair/X-Ray Head	15 in. x 27.25 in.
A880115	Disposable Barrier for Multi-Purpose Use	4 in. x 6 in.
65090001	DISPOSA-SHIELD® No. 1 Light Handles and Control Panels, A880115	4 in. x 6 in.
A88014	Disposable Barrier for Tray Size 10 ½” x 14 ½”	10.5 in. 14.5 in.
A88015	Disposable Barrier for Tray Size 12” x 17”	12 in. x 17 in.
A88016	Disposable Barrier for Dental Chair Head Rest	13 in. x 13 in.
65090004	DISPOSA-SHIELD® No. 4 Headrest Cover, A88016	13 in. x 13 in.
A88018	Disposable Barrier for Midwest RDH Freedom Inner Module	59 mm x 178 mm
A88019	Disposable Barrier for Midwest RDH Freedom with SmartMode Technology Inner Module	56.6 mm x 178
737007	Disposable Barrier for Standard Type Delivery Systems, Trial Pack for A88013	1.37 in. x 7.60 in.
90736	Disposable Barrier for Midwest RDH Freedom Inner Module, Trial Pack for A88018	59 mm x 178 mm
978079	Bebop Barrier Sleeve	2.5 in x 8.016 in.
050500	Universal Digital Sensor Covers – Bulk Pack	1.574 in. x 7.00 in.
550500	Universal Digital Sensor Covers	1.574 in. x 7.00 in.
550200	Large Sensor Cover (Soft Overbag Cover)	4.02 in. x 9.4 in.
550143	Tight Digital Sensor Cover –Size 1.5/2, 300-pack	8.881 in. x 1.772 in
055574	Tight Digital Sensor Cover –Size 1.5/2, 25-pack	8.881 in. x 1.772 in
055629	Tight Digital Sensor Cover -Size 1.5/ 2	8.881 in. x 1.772 in
550149	Tight Sensor Cover –Size 1, 300-pack	8.881 in. x 1.713 in

Part Number	Device Description	Size
055575	Tight Sensor Cover - Size 1, 25-pack	8.881 in. x 1.713 in
055630	Tight Sensor Cover –Size 1	8.881 in. x 1.713 in
120126	Sani-Shield® Disposable Barrier for Air/Water Syringe –Single Packs of 250	2.25 in. x 8.50 in.
130010	Sani-Shield® Disposable Barrier for Air/Water Syringe – 40 Single Packs of 250	2.25 in. x 8.50 in.
1300105	Sani-Shield® Disposable Barrier for Air/Water Syringe –Single Packs of 250	2.25 in. x 8.50 in.
644060	SmartLite® Max Disposable Barrier Sleeves	2.125 in. x 10.813 in.
644.50.030	SmartLite Focus Sleeve Refill	11 in. x 1.75 in.
EAPB100	Endo Activator Protective Barrier	
678079	digit® power Disposable Barrier Sleeves Refill	2.189 in. x 8.5 in.

7. Non-Clinical Performance Data

Test	Standard	Proposed Devices Disposable Barrier Sleeves and Covers	Predicate Device TIDIShield™ Curing Light Sleeve (K132953)
Biocompatibility Testing:			
In-Vitro Cytotoxicity	ANSI/AAMI/ISO 10993-5	Pass	Pass
Sensitization	ISO 10993-10	Pass	Pass
Irritation	ISO 10993-10	Pass	Pass
Performance Testing:			
Synthetic Blood Penetration	ASTM F1670/F1670M	Pass	Pass
Synthetic Blood Penetration at seams and non-continuous components	ASTM F1670/F1670M	Pass	Pass
Viral Penetration	ASTM F1671/ F1671M	Pass	Pass
Viral Penetration at seams and non-continuous components	ASTM F1671/ F1671M	Pass	Pass

Biocompatibility testing focused on cytotoxicity, levels of skin sensitization and oral mucosa irritation of the proposed devices, Disposable Barrier Sleeves and Covers. Below is a summary of the testing performed:

- ANSI AAMI ISO 10993-5 Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10 Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization

The performance of the proposed devices, Disposable Barrier Sleeves and Covers, met the requirements of the biocompatibility testing conducted to support substantial equivalence with the predicate, TIDIShield™ Curing Light Sleeve (K132953).

The performance testing (Bench) of the proposed devices, Disposable Barrier Sleeves and Covers, met the requirements of the non-clinical bench testing conducted to support substantial equivalence with the predicate, TIDIShield™ Curing Light Sleeve (K132953). Below is a summary of the testing performed:

- ASTM F1670/F1670M Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood
- ASTM F1671/ F1671M Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

Mechanical Property	Standard	Proposed Devices Disposable Barrier Sleeves and Covers	Predicate Device TIDIShield™ Curing Light Sleeve (K132953)
Tensile Strength	ASTM D882	0.02mm Acceptable 0.03mm Acceptable 0.05mm Comparable to Predicate	Acceptable for 0.05mm
Puncture Resistance	ASTM F1342/ F1342M	0.02mm Acceptable 0.03mm Acceptable 0.05mm Comparable to Predicate	Acceptable for 0.05mm
Tear Resistance	ASTM D1004	0.02mm Acceptable 0.03mm Acceptable 0.05mm Comparable to Predicate	Acceptable for 0.05mm

The range of mechanical properties for the samples is reported for the proposed devices, Disposable Barrier Sleeves and Covers. Below is a summary of the testing performed:

- ASTM D882 Standard Test Methods for Tensile Properties of Thin Plastic Sheeting
- ASTM F1342/ F1342M Standard Test Method for Protective Clothing Material Resistance to Puncture
- ASTM D1004 Standard Test Method for Tear Resistance (Graves Tear) of Plastic Film and Sheeting

The range of mechanical properties for the samples of the proposed devices, Disposable Barrier Sleeves and Covers, are comparable to those reported for the predicate device, TIDIShield™ Curing Light Sleeve (K132953), and support substantial equivalence with the predicate device, TIDIShield™ Curing Light Sleeve (K132953).

Clinical Performance Data.

No data from human clinical studies have been included to support the substantial equivalence of the proposed devices, Disposable Barrier Sleeves and Covers, as clinical studies are not required for this medical device.

8. Conclusion Regarding Substantial Equivalence

The proposed devices, Disposable Barrier Sleeves and Covers, are dental barrier sleeves and covers which are intended to serve as a disposable barrier for dental instruments and equipment. These disposable barrier sleeves and covers are non-sterile and are intended for single patient use only. The proposed devices, Disposable Barrier Sleeves and Covers, have the same intended use and indications for use and incorporate the same fundamental technology, as the predicate device, TIDIShield™ Curing Light Sleeve, cleared under premarket notification K132953. Test data to verify the performance of the proposed devices, Disposable Barrier Sleeves and Covers, have been provided including cytotoxicity, skin sensitization, oral mucosa irritation, synthetic blood penetration, synthetic blood penetration at seams and non-continuous components, viral penetration and viral penetration at seams and non-continuous components. The range of mechanical properties has been provided for puncture resistance, tear resistance, and tensile strength. The results of this testing, combined with the design, intended use and mechanical property comparison with the predicate device, support substantial equivalence with the predicate device, TIDIShield™ Curing Light Sleeve (K132953).