



Food and Drug Administration  
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September 27, 2016

Dentsply Sirona  
Helen Lewis  
Director, Corporate Regulatory Affairs  
221 West Philadelphia Street  
Suite 60  
York, Pennsylvania 17404

Re: K160825

Trade/Device Name: MIDWEST® RDH Freedom® Cordless Prophy System With  
SmartMode™ Technology

Regulation Number: 21 CFR 872.4200

Regulation Name: Dental Handpiece And Accessories

Regulatory Class: Class I

Product Code: EKX

Dated: August 29, 2016

Received: August 30, 2016

Dear Helen 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,

**Michael J. Ryan -S**

for Tina Kiang, Ph.D.

Acting 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)

Device Name

MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology

Indications for Use (Describe)

The MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology is a high-performance cordless prophylaxis handpiece with an optional wireless foot pedal for use with NUPRO Freedom® disposable prophy angles in a hygiene operatory to perform cleaning and polishing procedures on teeth.

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**  
**for**

**MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology**

Submitter Information:

Dentsply Sirona  
221 West Philadelphia Street  
Suite 60  
York, PA 17401

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

Date Prepared: 16 September 2016

Device Name:

- Proprietary Name: MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology
- Classification Name: Dental Handpiece and Accessories
- Common Name: Prophy System
- CFR Number: 21 CFR 872.4200
- Device Class: I
- Product Code: EKX

Predicate Device:

<b>Predicate Device Name</b>	<b>510(k)</b>	<b>Company Name</b>
MIDWEST® RDH Freedom® Cordless System	K110753	DENTSPLY International Inc.

Description of Device:

The proposed device, MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology, is a cordless handpiece which is intended for use by a dental clinician during dental cleaning and polishing procedures.

The proposed device, MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology, is comprised of an electric motor-driven prophylaxis cordless handpiece (consisting of an inner module and outer sheath), a direct current (DC) powered charging base for cordless handpiece, cradle for cordless handpiece, direct current (DC) power supply and cord, and uses proprietary disposable prophy angles (DPAs). The proposed device, MIDWEST® RDH Freedom® Cordless Prophy System

with SmartMode™ Technology, uses a USB mini connector to provide battery charging power to the charging base for the cordless handpiece and operates using Bluetooth low energy (BLE) wireless radio frequency. An optional wireless foot pedal is sold separately.

Accessories include single use, proprietary NUPRO Freedom® disposable prophylaxis angles [(cleared under premarket notification K030603 in April, 2003 by Pac-Dent International, Inc. as ProAngle™ Disposable Prophylaxis Angle (manufactured by Pac-Dent International, Inc.) and under premarket notification K954802 in November, 1995 by DENTSPLY International as Rite-Angle Disposable Prophylaxis Angles (manufactured by Angstrom Manufacturing, Inc.)] which are sold separately and available in a 90 degree angle and contra angle with multiple cup options: firm cup, soft cup, spiral cup, pedo (pediatric) cup, pointed tip and tapered brush. An optional wireless foot pedal (cleared under premarket notification K110753 in June, 2011 as MIDWEST RDH Freedom Cordless System) is sold separately.

The proposed device, MIDWEST® RDH Freedom® Cordless Prophylaxis System with SmartMode™ Technology, must be used with a Disposa-Shield® disposable barrier (cleared as Class II under premarket notification K160232 in June 2016 as Disposa-Shield Disposable Barrier for Midwest RDH Freedom with SmartMode Technology Inner Module), which is sold separately.

An FDA-Cleared lubricant can be used to lubricate the outer sheath nose of the proposed device, MIDWEST® RDH Freedom® Cordless Prophylaxis System with SmartMode™ Technology, only if the DPA does not spin freely. A coupler prevents lubricant from contacting the cordless handpiece inner module. If lubricant is applied, the outer sheath must be sterilized prior to use.

The cordless handpiece can be operated in SmartMode™ mode without using the optional wireless foot pedal (K110753). SmartMode™ Technology allows the output speed and torque of the cordless handpiece to be controlled by the amount of force the user applies from the disposable prophylaxis angle (DPA) (K030603; K954802) to the tooth without the use of the optional wireless foot pedal (K110753).

The cordless handpiece can also be operated by using the optional wireless foot pedal (K110753) and the amount of vertical displacement corresponds to the output speed of the cordless handpiece supplied to the DPA (K030603; K954802). The optional wireless foot pedal (K110753) operates using Bluetooth low energy (BLE) communication. Engaging the optional wireless foot pedal (K110753) activates the Bluetooth low energy (BLE) mode of both the cordless handpiece and the optional wireless foot pedal (K110753), and will override the SmartMode™ mode for operation of the cordless handpiece.

#### Indications for Use:

The Midwest® RDH Freedom® Cordless Prophylaxis System with SmartMode™ Technology is a high-performance cordless prophylaxis handpiece with an optional wireless foot pedal for use with NUPRO Freedom® disposable prophylaxis angles in a hygiene operatory to perform cleaning and polishing procedures on teeth.

Identification of Risk Analysis Method

Risk analysis was performed on the MidWest® RDH Freedom® Cordless Propphy System with SmartMode™ Technology utilizing an FMEA process based on ISO 14971:2007 (Corrected 2007-10-01). The results of the risk analysis performed on the MidWest® RDH Freedom® Cordless Propphy System with SmartMode™ Technology concluded that all device design controls and process controls will be able to mitigate known potential failures and effects. In addition, performance testing, electrical safety and electromagnetic compatibility testing were performed to mitigate other potential risks. New biocompatibility testing was not required as the materials, manufacturing methods, and sterilization for the outer sheath are the same as the predicate device, MidWest® RDH Freedom® Cordless System (K110753). An FDA-cleared lubricant can be used to lubricate the outer sheath nose of the proposed device, MIDWEST® RDH Freedom Cordless Propphy System with SmartMode™ Technology, only if the DPA does not spin freely. A coupler prevents lubricant from contacting the cordless handpiece inner module. If lubricant is applied, the outer sheath must be sterilized prior to use.

Substantial Equivalence:

<b><u>ELEMENT</u></b>	<b><u>PROPOSED DEVICE:</u></b> <b>MIDWEST® RDH FREEDOM® CORDLESS PROPHY SYSTEM WITH SMARTMODE™ TECHNOLOGY</b>	<b><u>PREDICATE DEVICE:</u></b> <b>MIDWEST® RDH FREEDOM™ CORDLESS SYSTEM</b>	<b><u>DIFFERENCES WITH PREDICATE DEVICE</u></b>
<b>510(k)</b>	K160825	K110753	N/A
<b>Indications for Use</b>	The Midwest® RDH Freedom® Cordless Propphy System with SmartMode™ Technology is a high-performance cordless prophylaxis handpiece with an optional wireless foot pedal for use with NUPRO Freedom® disposable prophylaxis angles in a hygiene operatory to perform cleaning and polishing procedures on teeth.	The Midwest® RDH Freedom™ Cordless System is a high-performance cordless prophylaxis handpiece with a wireless foot pedal for use with Freedom® disposable prophylaxis angles in a hygiene operatory to perform cleaning and polishing procedures on teeth.	The wireless foot pedal is an option rather than a requirement for operation of the cordless handpiece for the proposed device. Use of SmartMode™ provides the same level of operation and does not have a negative effect on the performance of the device when used as labeled.
<b>Accessories</b>	NUPRO Freedom® Disposable Propphy Angles	NUPRO Freedom® Disposable Propphy Angles	None
	Removable, autoclavable outer sheath	Removable, autoclavable outer sheath	Elimination of aesthetic color ring and pins for alignment with

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			cordless handpiece inner module does not impact substantial equivalence.
	Power supply and cord – AC/DC wall plug adapter	Power supply and cord– AC/DC wall plug adapter	None
	Cradle for cordless handpiece	Cradle for cordless handpiece	None
	Optional wireless foot pedal	Required wireless foot pedal	User has the choice to use the optional wireless foot pedal for proposed device but is required to use the predicate device foot pedal.
<b>Material Composition</b>	<ul style="list-style-type: none"> <li>• Outer Sheath – Aluminum with stainless steel tip</li> <li>• Cordless Handpiece Inner Module Housing – Plastic</li> <li>• Charging Base for Cordless Handpiece Housing – Plastic</li> <li>• Cradle for Cordless Handpiece – Plastic</li> <li>• Foot Pedal Housing – Plastic</li> </ul>	<ul style="list-style-type: none"> <li>• Outer Sheath – Aluminum with stainless steel tip</li> <li>• Cordless Handpiece Inner Module Housing – Plastic</li> <li>• Charging Base for Cordless Handpiece Housing – Plastic</li> <li>• Cradle for Cordless Handpiece – Plastic</li> <li>• Foot Pedal Housing - Plastic</li> </ul>	None
<b>Cordless Handpiece Control</b>	The cordless handpiece can be controlled without a foot pedal via SmartMode™ Technology, or with an optional wireless foot pedal.	The cordless handpiece is controlled exclusively by the required wireless foot pedal.	The wireless foot pedal is an option rather than a requirement for operation of the cordless handpiece for the proposed device. Use of SmartMode™ provides the same level of operation

<b><u>ELEMENT</u></b>	<b><u>PROPOSED DEVICE: MIDWEST® RDH FREEDOM® CORDLESS PROPHY SYSTEM WITH SMARTMODE™ TECHNOLOGY</u></b>	<b><u>PREDICATE DEVICE: MIDWEST® RDH FREEDOM™ CORDLESS SYSTEM</u></b>	<b><u>DIFFERENCES WITH PREDICATE DEVICE</u></b>
			and does not have a negative effect on the performance of the device when used as labeled.
<b>SmartMode™ Technology</b>	This device has SmartMode™ Technology. The output speed and torque of the cordless handpiece are controlled by the amount of force the user applies from the DPA to the tooth, without the use of the optional wireless foot pedal.	This device does not have SmartMode™ Technology. The output speed and torque of the cordless handpiece are controlled by the amount of force applied to the required wireless foot pedal.	Addition of SmartMode™ feature allows the user to conduct procedures without use of the wireless foot pedal, provides the same level of operation and does not have a negative effect on the performance of the device when used as labeled.
<b>Cordless Handpiece Bluetooth Wireless Technology Capabilities</b>	The cordless handpiece has Bluetooth low energy (BLE) wireless technology capabilities when used with the optional wireless foot pedal.	The cordless handpiece has Zigbee wireless technology capabilities when used with the required wireless foot pedal	Similar wireless technology which results in the same level of operation.
<b>Cordless Handpiece Maximum Speed; Maximum Torque using Foot Pedal</b>	Optional Wireless Foot Pedal no load 3400±300 rpm  9 mNm maximum load 3000±10% rpm	Required Wireless Foot Pedal no load 3300±300 rpm  10 mNm maximum load 3000±10% rpm	When used with the optional wireless foot pedal at no load, the cordless handpiece of the proposed device provides equivalent speed compared to the handpiece speed at no load of the predicate device which uses the required wireless foot pedal.
<b>Cordless Handpiece Maximum</b>	9 mNm maximum load 3000±10% rpm	SmartMode™ technology is not offered.	Addition of SmartMode™ technology allows



<b><u>ELEMENT</u></b>	<b><u>PROPOSED DEVICE:</u></b> <b>MIDWEST® RDH FREEDOM® CORDLESS PROPHY SYSTEM WITH SMARTMODE™ TECHNOLOGY</b>	<b><u>PREDICATE</u></b> <b><u>DEVICE:</u></b> <b>MIDWEST® RDH FREEDOM™ CORDLESS SYSTEM</b>	<b><u>DIFFERENCES</u></b> <b><u>WITH</u></b> <b><u>PREDICATE</u></b> <b><u>DEVICE</u></b>
<b>Speed; Maximum Torque using SmartMode™ (without Foot Pedal)</b>			the user to perform cleaning procedures without the use of a wireless foot pedal.
<b>Cordless Handpiece Interface</b>	The cordless handpiece has a user pushbutton that controls mode selection: SmartMode™ or Foot Pedal Use	The handpiece has one user interface: Foot Pedal Use.	Addition of mode control and ability to make a selection on the cordless handpiece allows the user to see the current mode and to change modes.
<b>Cordless Handpiece On/Off Switch</b>	The cordless handpiece has a user pushbutton that controls power on/off.	The cordless handpiece does not have a power on/off control.	The proposed device has a user pushbutton on the cordless handpiece that controls power on/off and offers the user direct control of the power status.
<b>Cordless Handpiece Power Light</b>	The indicator “on” light is illuminated when the power is on.	The indicator “on” light is illuminated when the power is on.	None
<b>Cordless Handpiece Visual Status Indicators</b>	A range of steady and blinking LED indicator lights on the cordless handpiece display the handpiece status  Mode Status: <ul style="list-style-type: none"> <li>• Standby = Green</li> <li>• SmartMode™ Operation = Purple</li> <li>• Foot Mode Operation = Blue</li> <li>• Internal Temperature of 55°C or above = Orange.</li> </ul>	A range of steady and blinking LED indicator lights on the cordless handpiece display the handpiece status  Mode Status: <ul style="list-style-type: none"> <li>• Standby = Green</li> <li>• Internal Temperature of 55°C or above = Orange</li> </ul>	The increased number of indicator colors on the proposed device provides more information to user regarding mode status, charging status, level of charge, synchronization status, and over-temperature

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	Battery State of Charge: <ul style="list-style-type: none"> <li>• Level of Charge = Green</li> <li>• Needs to be Charged = Orange</li> </ul> Synchronization Status: <ul style="list-style-type: none"> <li>• Ready = Blue</li> <li>• Success = Green</li> <li>• Unsuccessful = Orange</li> </ul>	Battery State of Charge: <ul style="list-style-type: none"> <li>• Level of Charge = Green</li> <li>• Needs to be Charge = Orange</li> </ul> Synchronization Status: <ul style="list-style-type: none"> <li>• Positioned Properly in charging base = Green</li> <li>• Ready = Scrolling Green and Orange</li> <li>• Successful = Green</li> <li>• Unsuccessful = Orange</li> </ul>	condition.
<b>Cordless Handpiece Visual Alarm</b>	Cordless handpiece Mode indicator shows Orange when internal printed circuit board (PCB) temperature is above normal. Operator should refrain from using the handpiece for several minutes. The light will turn off when the temperature returns to normal.	Cordless handpiece LED indicator light shows Orange when internal PCB temperature is above normal. Operator should refrain from using the handpiece for several minutes. The light will turn off when the temperature returns to normal.	None
<b>Cordless Handpiece Power</b>	The cordless handpiece can be turned on and off manually.	The cordless handpiece does not have an on/off button. The cordless handpiece will not activate when the required wireless foot pedal is more than 30 degrees from horizontal.	The addition of an on/off button on the proposed device allows the user to have control over power status of the cordless handpiece.

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	When not in the charging base for cordless handpiece, the cordless handpiece enters a low current mode after 1 minute of inactivity. The cordless handpiece “wakes-up” when the On/Off/Mode button on the cordless handpiece is depressed or automatically when it is picked up.	When not in the charging base for cordless handpiece, the cordless handpiece will enter a low current (sleep) mode 1 within 1 minute of inactivity. “Wake-up” occurs by moving the handpiece by 45 degrees in any axis.	Actions to initiate “wake-up” of the devices differ slightly but result in the same operation and do not affect substantial equivalence.
	When not in the charging base for cordless handpiece, the cordless handpiece enters a “Sleep” mode after 24 hours of inactivity. The cordless handpiece “wakes-up” when the On/Off/Mode button on the cordless handpiece is depressed, or when placed in the charging base for the cordless handpiece.	When not in the charging base for cordless handpiece, the cordless handpiece enters a lower current (sleep) mode 2 within a time period of inactivity after 7 days but not more than 14 days of inactivity. “Wake-up” occurs by placing the handpiece on the charger for 5 seconds to enter normal operating mode.	The proposed handpiece enters a lower current state after 1 day rather than 7 days for the predicate. This permits the battery saving operation to initiate more quickly. Actions to initiate “wake-up” of the devices differ slightly but result in the same operation and do not affect substantial equivalence.
<b>Cordless Handpiece Battery Recharging Capability</b>	The 3.7 volt Lithium Ion handpiece battery is recharged by placing the cordless handpiece in the included charging base for the cordless handpiece.	The 3.7 volt Lithium Ion handpiece battery is recharged by placing the cordless handpiece in the included charging base for the cordless handpiece.	None
<b>Cordless Handpiece Power Connector</b>	A 5 volt power supply and cord provides battery charging power through a USB mini connector to the charging base for the	A 5 volt power supply and cord provides battery charging power through a barrel connector to the	The proposed device provides power through a USB mini connector rather

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	cordless handpiece.	charging base for the cordless handpiece.	than a barrel connector
<b>Handpiece Battery Power</b>	The handpiece battery has sufficient power to complete a day's worth of hygiene procedures on a single charge (average of 10 procedures of an average 3 minutes each, or 30 minutes total).	The handpiece battery has sufficient power to complete a day's worth of hygiene procedures on a single charge (average of 10 procedures of an average 3 minutes each, or 30 minutes total).	None
<b>Handpiece Battery Quick Charge</b>	The handpiece battery permits the system to have the capability of completing one typical 3 minute cleaning procedure after only fifteen minutes of charging.	The handpiece battery permits the system to have the capability of completing one typical 3 minute cleaning procedure after only fifteen minutes of charging.	None
<b>Handpiece Battery Replacement</b>	The handpiece rechargeable battery can be replaced by factory personnel only.	The handpiece rechargeable battery can be replaced by factory personnel only.	None
<b>Outer Sheath</b>	Includes removable, autoclavable outer sheath to reduce the risk of patient cross-contamination.	Includes removable, autoclavable outer sheath to reduce the risk of patient cross-contamination.	None
<b>Outer Sheath Surface</b>	The outer sheath includes a roughened surface for grip.	The outer sheath includes a roughened surface for grip.	None
<b>Outer Sheath Housing Design</b>	The outer sheath housing has an angled cut design connection to the cap with an angled termination of the shot blast grip area.	The outer sheath housing has a swoop cut design connection to the cap with a straight termination of the shot blast grip area.	The angled cut design of the proposed device is an aesthetic choice and does not affect substantial equivalence.
<b>Outer Sheath Housing Removal</b>	The outer sheath housing does not have an aesthetic color ring and does not have pins. The outer sheath	The outer sheath housing has a rubber aesthetic color ring to cover press fit pins that are used for	The proposed device does not have the aesthetic color ring covering

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	is removed by holding the cap to rotate and slide the outer sheath up the plastic ramp of the handpiece inner module or to pull the sheath straight.	the twist-to-remove sheath design.	press fit pins on the predicate. The plastic ramp on the cordless handpiece inner module on the proposed device serves the same function as the press fit pins on the predicate outer sheath. Removal of the press fit pins eliminates the need for the aesthetic color ring, the requirement for the user to remove the color ring from the outer sheath, and to sterilize the color ring and outer sheath separately and does not affect substantial equivalence. Elimination of the color ring and pins from the outer sheath of the proposed device does not affect substantial equivalence.
<b>Foot Pedal Wireless Technology Capabilities</b>	The optional wireless foot pedal has Bluetooth Low Energy (BLE) wireless technology capabilities when used with the cordless handpiece.	The required wireless foot pedal has Zigbee wireless technology capabilities when used with the cordless handpiece.	Bluetooth wireless radio frequency provides the same operational capabilities as the predicate, and does not affect substantial equivalence.

<b><u>ELEMENT</u></b>	<b><u>PROPOSED DEVICE:</u></b> <b>MIDWEST® RDH FREEDOM® CORDLESS PROPHY SYSTEM WITH SMARTMODE™ TECHNOLOGY</b>	<b><u>PREDICATE DEVICE:</u></b> <b>MIDWEST® RDH FREEDOM™ CORDLESS SYSTEM</b>	<b><u>DIFFERENCES WITH PREDICATE DEVICE</u></b>
<b>Foot Pedal Visual Status Indicators</b>	<p>A range of steady and blinking LED indicator lights in the optional wireless foot pedal display the foot pedal mode status in 3 different colors:</p> <ul style="list-style-type: none"> <li>• Ready to Sync = Blue</li> <li>• Successful Sync = Green</li> <li>• Sync not Successful = Orange</li> </ul>	<p>A range of steady and blinking LED indicator lights in the required wireless foot pedal display the foot pedal mode status in 2 different colors:</p> <ul style="list-style-type: none"> <li>• Ready to Sync = Orange</li> <li>• Successful Sync = Green</li> <li>• Sync not Successful = Orange</li> </ul>	<p>Proposed device optional wireless foot pedal shows the foot pedal state of charge and synchronization state. Proposed device cordless handpiece does not display optional wireless foot pedal state of charge but does show synchronization state. For the predicate, the required wireless foot pedal state of charge was shown on the predicate handpiece. There is no negative impact on substantial equivalence. The addition of the color LED display provides more information to user regarding mode and charging status.</p>
	<p>A range of steady and blinking LED indicator lights in the optional wireless foot pedal display the foot pedal battery state of charge in 2 different colors:</p> <ul style="list-style-type: none"> <li>• Charged = Green</li> <li>• Requires Charging = Orange</li> </ul>	<p>Battery state of charge is not shown on the required wireless foot pedal, but is shown by an LED indicator light on the cordless handpiece:</p> <ul style="list-style-type: none"> <li>• Standby = Green</li> <li>• Requires Charging = Orange</li> </ul>	
<b>Foot Pedal Battery</b>	<p>The optional wireless foot pedal includes a rechargeable Lithium Ion (Lithium Cobalt Dioxide) battery, with a protection circuit.</p>	<p>The required wireless foot pedal includes a rechargeable Lithium Ion (Lithium Cobalt Dioxide) battery, with a protection circuit.</p>	None
<b>Foot Pedal Recharging Capability</b>	<p>The 3.7 volt Lithium Ion battery for the optional wireless foot pedal can be recharged multiple times by inclusion of a power supply and cord.</p>	<p>The 3.7 volt Lithium Ion battery for the required wireless foot pedal can be recharged multiple times by inclusion of a power supply and cord.</p>	None

<b><u>ELEMENT</u></b>	<b><u>PROPOSED DEVICE:</u></b> <b>MIDWEST® RDH FREEDOM® CORDLESS PROPHY SYSTEM WITH SMARTMODE™ TECHNOLOGY</b>	<b><u>PREDICATE DEVICE:</u></b> <b>MIDWEST® RDH FREEDOM™ CORDLESS SYSTEM</b>	<b><u>DIFFERENCES WITH PREDICATE DEVICE</u></b>
<b>Foot Pedal Readiness</b>	The optional wireless foot pedal enters low current mode after approximately 1 minute of inactivity; wake-up occurs when the foot pedal cover is depressed.	The required wireless foot pedal enters low current (sleep) mode 1 within 1 minute of inactivity; wake-up occurs when the cover is depressed by approximately 25%.	The optional foot pedal of the proposed device enters battery-saving mode at the same point at the predicate but does not have a lower current (sleep) mode. There is no impact on substantial equivalence.
	The optional wireless foot pedal does not offer an even lower current (sleep) mode.	The required wireless foot pedal enters low current (sleep) mode 2 after 7 days but not more than 14 days of inactivity; wake-up occurs when the cover is depressed by approximately 25%.	
<b>Foot Pedal Safety Mechanism</b>	The optional wireless foot pedal has a power button situated on the bottom side of the unit to prevent accidentally turning on the foot pedal and does not require a safety mechanism.	The required wireless foot pedal does not have a power button. If the required wireless foot pedal is more than 30 degrees from horizontal, it will not request that the cordless handpiece rotate its motor, even when pressed.	The presence and location of a power button on the optional wireless foot pedal offers the user control of power being turned on for the optional wireless foot pedal.
<b>Sheath Sterilization</b>	Outer sheath steam sterilizable at 135°C	Outer sheath steam sterilizable at 135°C	None
<b>Material Compatibility</b>	Biocompatibility meets requirements	Biocompatibility meets requirements	None
<b>Electromagnetic Compatibility and Electrical Safety</b>	Meets requirements	Meets requirements	None

The difference in Indications for Use between the proposed device, MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology, and the predicate device, MIDWEST® RDH Freedom® Cordless System (K110753) is that use of the wireless foot pedal (K110753) is optional for the proposed device, MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology.

Use of SmartMode™ technology to operate the cordless handpiece meets the same intended use as that of the predicate device, MIDWEST® RDH Freedom® Cordless System (K110753). When activated, SmartMode™ mode operates the cordless handpiece with similar speeds and torques as the predicate device, MIDWEST® RDH Freedom® Cordless System (K110753), and does not affect the substantial equivalence of the device when used as labeled.

The user has the option to use an optional wireless foot pedal (K110753) with the proposed device, MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology, which is similar to the required foot pedal (K110753) of the predicate device, MIDWEST® RDH Freedom® Cordless System (K110753).

The MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology, and the predicate device, MIDWEST® RDH Freedom® Cordless System (K110753) use the same materials and energy source with essentially the same design.

#### Non-Clinical Performance Data:

Because the proposed device, MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology, and the predicate device, MIDWEST® RDH Freedom® Cordless System (K110753) use the same materials and energy source with essentially the same design, new biocompatibility testing was not required for the outer sheath to support substantial equivalence. Biocompatibility testing was submitted with the predicate device, MIDWEST® RDH Freedom® Cordless System, and cleared under premarket notification K110753 in June, 2011.

An FDA-Cleared lubricant can be used to lubricate the outer sheath nose of the proposed device, MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology, only if the DPA does not spin freely. A coupler prevents lubricant from contacting the cordless handpiece inner module. If lubricant is applied, the outer sheath should be sterilized prior to use.

The NUPRO Freedom® disposable prophy angles were previously cleared under premarket notification K030603 in April, 2003 by Pac-Dent International, Inc. as ProAngle™ Disposable Prophy Angle (manufactured by Pac-Dent International, Inc.) and under premarket notification K954802 in November, 1995 by DENTSPLY International as Rite-Angle Disposable Prophy Angles (manufactured by Angstrom Manufacturing, Inc.

An optional wireless foot pedal was cleared under premarket notification K110753 in June, 2011 by DENTSPLY International Inc. as MIDWEST® RDH Freedom® Cordless System.

A Disposa-Shield® disposable barrier was cleared as Class II under premarket notification K160232 in June 2016 as Disposa-Shield Disposable Barrier for Midwest RDH Freedom with SmartMode Technology Inner Module.



<b>Comparison of Performance Data/Physical Properties</b>				
<b>Physical Property</b>	<b>Test Description</b>	<b>Standard</b>	<b>Proposed Device</b> Midwest® RDH Freedom® Cordless Prophy System with SmartMode™ Technology(K160825)	<b>Predicate Device</b> Midwest® RDH Freedom® Cordless System (K110753)
TP-566 Bluetooth Compatibility	Verify Foot Pedal can communicate with handpiece at distances of 15 Feet, when exposed to RF interference from other systems.	DENTSPLY Professional Internal Test Method	Pass Bluetooth	Pass Zigbee
TP-513 SmartMode™ Performance	Verify performance of SmartMode, including ability of the user to override and motor stop features.	DENTSPLY Professional Internal Test Method	Pass	N/A*
TP-602 SmartMode Technology Performance with Various Types of DPA's	Verify performance of SmartMode when using different types of DPA's.	DENTSPLY Professional Internal Test Method	Pass	N/A*
TP-509 Cordless Handpiece Inner Module Push Button, Battery Indicator, Sleep Mode Functionality	Verify functionality of the Inner Module button and battery indicator and proper functionality of sleep mode.	DENTSPLY Professional Internal Test Method	Pass	N/A**
TP-507 Speed Control and Level of Usage on a Single Charge	Verify that the Inner Module capable of performing one day's worth of procedures (10 procedures) on a single charge.	DENTSPLY Professional Internal Test Method	Pass	Pass

<b>Comparison of Performance Data/Physical Properties</b>				
<b>Physical Property</b>	<b>Test Description</b>	<b>Standard</b>	<b>Proposed Device</b> Midwest® RDH Freedom® Cordless Prophy System with SmartMode™ Technology(K160825)	<b>Predicate Device</b> Midwest® RDH Freedom® Cordless System (K110753)
TP-506 Speed Torque Performance	Verify that the speed performance of the Inner Module meets specifications when various loads are applied to simulate actual use.	DENTSPLY Professional Internal Test Method	Pass	Pass
TP-515 Outer Sheath Insertion/Extraction Forces	Verify that the force required to insert and extract the Outer Sheath from the Inner Module is acceptable per the design specifications.	DENTSPLY Professional Internal Test Method	Pass	Pass
TP-505 System Component Physical Attributes	Verify that the general size, shape, weight, and center of gravity attributes are acceptable per the design specifications.	DENTSPLY Professional Internal Test Method	Pass	Pass
TP-517 Cordless Handpiece Inner Module Liquids Ingress Test	Verify that fluid does not accumulate in the Inner Module.	DENTSPLY Professional Internal Test Method/IEC	Pass	Pass
TP-508 Foot Pedal Performance	To verify foot pedal battery capacity and the ability for it to operate on a fully drained battery when plugged in to the power supply.	DENTSPLY Professional Internal Test Method	Pass	Pass

Performance testing focused on verification of design, prophylaxis cleaning and polishing performance, and safety of the MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology. Below is a list of the standards to which testing was performed:

- AAMI ANSI ES 60601-1 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance (2005; reapproved 2012)
- IEC 60601-1-2 Medical Electrical Equipment PART 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility (2007)
- FDA - Dental Handpieces – Premarket Notification [510(k)] Submissions
- FDA - Guidelines for the Content of Premarket Submissions for Software Contained in Medical Devices- Software Validation

The results of these performance tests support the substantial equivalence of the proposed device, MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology, with the predicate device, MIDWEST® RDH Freedom® Cordless System (K110753).

#### Clinical Performance Data.

Professional evaluations were conducted considering the proposed device intended use, users, and use environments. All studies were completed by practicing registered dental hygienists on dental typodonts to simulate intended use, users, and use environments.

As a result of multiple professional evaluations with typodonts and clinical human factor validations involving performance testing, data was gathered to support our assessment that the risk of potential for tissue damage has been adequately mitigated and no unacceptable risks or unacceptable use related hazards related to SmartMode™ Technology were identified.

#### Conclusion Regarding Substantial Equivalence

The proposed device, MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology, is a high-performance cordless prophylaxis handpiece with an optional wireless foot pedal (K110753) for use with proprietary disposable prophy angles (K030603; K954802) which is intended to clean and polish teeth. The MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology, has the same intended use, incorporates the same fundamental technology, and has similar indications for use as the predicate, MIDWEST® RDH Freedom® Cordless Prophy System (K110753). MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology, uses the same material and energy source, and has essentially the same design as the predicate device, MIDWEST® RDH Freedom® Cordless System (K110753).

Use of SmartMode™ technology to operate the cordless handpiece meets the same intended use as that of the predicate device, MIDWEST® RDH Freedom® Cordless System (K110753). When activated, SmartMode™ drives operation of the cordless handpiece with similar speeds and torques as the predicate device, MIDWEST® RDH Freedom® Cordless System (K110753), and does not affect the device when used as labeled. The user has the option to use an optional wireless foot pedal (K110753) with the

proposed device, MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology, which is similar to the required foot pedal (K110753) of the predicate device, MIDWEST® RDH Freedom® Cordless System (K110753).

Test data to verify the performance of the proposed device, MIDWEST® RDH Freedom® Cordless Prophy System with SmartMode™ Technology, have been provided including: wireless functionality; SmartMode™ performance; module and indicator functionality; speed control and level of usage for a single charge; speed, current and torque; cordless handpiece inner module and outer sheath insertion/extraction forces; system physical dimensions and weight; liquids ingress; and foot pedal performance.

The results of this performance testing, combined with the design and intended use comparison with the predicate device, MIDWEST® RDH Freedom® Cordless System (K110753), support substantial equivalence to, the predicate device, MIDWEST® RDH Freedom® Cordless System (K110753).