December 2, 2021

Inter-Med, INC.
Brett Arand
Senior Product Development Engineer
2200 South Street
Racine, Wisconsin 53404

Re: K211721-S002
Trade/Device Name: PS System
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: NYL
Dated: May 21, 2021
Received: June 4, 2021

Dear Brett Arand:

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 Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K211721

Device Name
PS System

Indications for Use *(Describe)*

The PS System is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures.

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-K211721
PS System

1. Applicant

Inter-Med / Vista Dental Products
2200 South Street
Racine, WI, USA 53404

Contact Person: Brett Arand
Telephone Number: (262) 633-0755
Fax Number: (262) 636-9760
Email: barand@vista-dental.com

Date Prepared: November 3rd, 2021
Prepared By: Brett Arand

2. Device Name

Proprietary Name: PS System
Classification Name: Handheld controller, air-powered, root canal irrigation
CRF Number: 872.4200
Product Code: NYL
Device Class: Class I

3. Predicate Device

The PS System is substantially equivalent to the legally marketed device Endo Vac Apical Negative Pressure Irrigation System (K140685), submitted by Sybron Endo and cleared on July 2nd, 2014, product code NYL.

4. Device Description

The PS System presents a clinically effective way to irrigate the entire canal space during root canal treatments. The PS System is a closed system negative pressure irrigation apparatus that draws fluid through the individually placed cannula toward the coronal chamber by way of evacuation that is controlled independently through the dental chair vacuum system, eliminating the risk of apical irrigant extrusion during root canal procedures. The PS System creates a closed system by establishing an air tight seal between the tooth and stage via a light-curable barrier. The PS System is designed to accommodate the full range of tooth and root canal anatomy and is offered in three specific procedural kits based on the type of tooth to be treated: anterior, premolar, and molar.

The PS System is packaged in procedural kits composed of the following items:

Table 5-1: PS System Components and Regulatory Status

PS System Component	Class	Product Code	FDA Status
1. Stage (molar, premolar or anterior)	1	NYL	Subject of new 510(k)
2. Placement tool (molar, premolar or anterior)			
3. Cannula set with connection tubing (molar, premolar or anterior)			
4. Vacuum Line with suction adapter			
5. Light Curable Barrier	1	EIE	Exempt per 21 CFR 872.6300
6. Sodium hypochlorite with wetting agents (i.e. Chlor-Xtra)	U	KJJ	Reference to Chlor-Xtra cleared in K082470 in light of completed Chlor-Xtra Plus 8% NaOCl Regulatory Change Assessment dated 10/27/2021 included in Section 11 – Device DescriptionCleared via K082470
7. SmearOFF	U	KJJ	Cleared via K193409
8. Syringe	1	EIC	Premarket notification exempt per 21 CFR 872.4565
9. Application Tips	1	EIC	Premarket notification exempt per 21 CFR 872.4565

This is the only 510(k) for the PS System medical device, no prior 510(k)s have been submitted.

5. Intended Use / Indication for Use

The PS System is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures.

6. Technological Characteristics and Substantial Equivalence

The technological characteristics of the PS System are very similar to the predicate EndoVac System (K140685). The PS System and the predicate EndoVac System (K140685) perform the same function, which is a method to deliver irrigant, rinse and evacuate during root canal procedures. A comprehensive comparison of technological characteristics and substantial equivalence between the systems is provided below.

Table 5-2: Predicate and Proposed Device Comparison Table

	Predicate Device **EndoVac System**	**Proposed Device** **PS System**
510(k)	K140685	K211721
Trade name	EndoVac Apical Negative Pressure Irrigation System	PS System (Molar, Premolar, Anterior)
Class	Class 1	Class 1
FDA Classification Name and CFR Number	Handheld controller, Air-Powered, Root Canal Irrigation 872.4200	Handheld controller, Air-Powered, Root Canal Irrigation 872.4200
Product code	NYL	NYL
Indication for use / intended use	The EndoVac system is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures.	The PS System is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures.
Target Users	Licensed Dental Professionals	Licensed Dental Professionals
Anatomical site	Oral cavity / Isolated tooth	Oral cavity / Isolated tooth

	Predicate Device **EndoVac System**	**Proposed Device** **PS System**
Device Components	Syringes, Multi-Port Adapter, Master Delivery Tip, Fingerpiece, Handheld controller, MicroCannula and MacroCannula, Connection tubing	Stage (molar, premolar or anterior), Cannula with Connection Tubing (molar, premolar or anterior), Vacuum Line with suction adapter, VacuSeal Light Curable Barrier, Sodium hypochlorite with wetting agents (i.e. Chlor-Xtra), SmearOFF, Syringes and Application Tips
Vacuum Connection	Multi-Port Adapter	Suction Adapter (fits both HVE and LVE)
Suction Adapter Dimensions	The Multi-Port Adapter critical to functionality dimension in this component is the Outer Diameter (OD) due to compatibility with dental chair high evacuation line (OD = 0.434 in)	The Suction Adapter critical to functionality dimension in this component is the Outer Diameter (OD) due to compatibility with dental chair evacuation line HVE adapter: 0.438 in ± 0.01 in LVE adapter: 0.25 in ± 0.01 in

	Predicate Device **EndoVac System**	**Proposed Device** **PS System**
Cannula Dimensions	MicroCannula critical to functionality dimension in this component is the OD due to the clinical application into the root canal cleaning procedure (OD = 0.0125 to 0.0118 in)	The Cannula critical to functionality dimension in this component is the OD due to the clinical application into the root canal cleaning procedure (OD = 0.0125 to 0.0118 in)
Cannula Working Length	MicroCannula working length is from 14 to 30 mm ± 0.5 mm	Cannula working length is greater than 30mm
Cannula Material	MicroCannula: AISI 304 Stainless Steel	AISI 304 Stainless Steel
Mode of Operation	Manually operated	Manually operated
Fluid Delivery System	Manual operation of syringe plunger (i.e. positive pressure from user)	Manual operation of the dental chair vacuum system (i.e. negative pressure suction from dental chair vacuum)
Liquids & Storage	• 20 ml syringe NaOCl • 3 ml syringe EDTA	• 100mL (molar), 60mL (pre-molar), 40mL (anterior) solution pouch Chlor-Xtra Plus • 3ml syringe SmearOFF

	Predicate Device **EndoVac System**	**Proposed Device** **PS System**
Unclogging Mechanism	Requires MacroCannula and MicroCannula to be disconnected from the vacuum line. The MacroCannula and MicroCannula are independently connected to another syringe and positive pressure is applied to dislodge and unclog any debris.	The cannula are connected to a syringe and positive pressure is applied to dislodge and unclog any debris by rotating stop-cock on tubing manifold, however since fluid is drawn out of the cannula and not through the cannula clogging is drastically reduced.
Cross contamination (cleaning, disinfection, sterilization)	Meet Requirements Patient contacting portion is autoclavable	All components are non-sterile and single use
Shelf-Life	NA, no solutions included	Shelf life is 24 months
Biocompatibility Testing / Analysis Performed	Meets Requirements	All components that make patient contact have been evaluated according to ISO 7405 / ISO 10993-1 and meet requirements
Recommended Irrigation Time	Per manufacturer's instruction for use there are 3 phases of EndoVac irrigation / evacuation:	There are 2 phases of PS System irrigation / evacuation:

	Predicate Device **EndoVac System**	**Proposed Device** **PS System**
	(1) Gross evacuation during orifice expansion and between instrument changes, as needed (2) Macro evacuation after complete instrumentation, 30 second for each canal (3) Micro evacuation at full WL, 3 cycles each 70-90 seconds for each canal. Total irrigation time per canal is 250 seconds, therefore 4 roots: 1000 seconds (16:40 minutes)	(1) Gross evacuation during orifice expansion and between instrument changes, as needed (2) Multi-cannular irrigation once stage has been sealed, Total irrigation time for any number of canals is approximately 15-20 minutes
Prescription / OTC	Prescription	Prescription

Applicable Standards

ISO 7405 – Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
ISO 14971 – Application of Risk Management to Medical Devices
ISO 80369-7 – Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
ISO 10271 – Dentistry - Corrosion test methods for metallic materials

7. Non-Clinical Performance Testing and Compliance

The technological characteristics of the PS System are very similar to the predicate EndoVac (K140685) negative pressure irrigation system. The PS System and the predicate EndoVac System (K140685) perform the same function, which is a method to

deliver irrigant, rinse and evacuate during root canal procedures. The following performance tests were conducted as part of design verification:

- Suction Flow Rate Performance
- Critical Dimensions for Clinical Performance Analysis
- Corrosion Testing
- Simulated Canal Performance Testing
- Shelf Life Verification
- Biocompatibility Analysis
- Transit Testing
- Additive Manufacturing Summary Document

8. Clinical Performance Data

Clinical performance testing has not been performed for the PS System.

9. Conclusion as to Substantial Equivalence

The proposed PS System and the predicate EndoVac System (K140685) have the same Indications for Use (besides trade name), which is, for the delivery and evacuation of endodontic irrigation solutions during root canal procedures. The PS System and the predicate EndoVac System (K140685) perform the same function, which is a method to deliver irrigant, rinse and evacuate during root canal procedures. The PS System and the EndoVac System are both negative pressure irrigation apparatuses that reduce the risk of apical extrusion compared to convention positive pressure syringe irrigation.

The technological characteristics of the PS System are very similar to the predicate EndoVac System (K140685). The proposed PS System is substantially equivalent to the predicate EndoVac System (K140685) based on design, performance, technological characteristics use of biocompatible materials, indications for use and the intended use. Any noted differences in technological characteristics between the proposed and predicate devices do not raise any new questions of safety and effectiveness. Based on extensive comparative analysis and testing the PS System is substantially equivalent to the predicate EndoVac System (K140685).