April 26, 2018

Pelton & Crane
Frank Ray
Regulatory Affairs Manager
11727 Fruehauf Drive
Charlotte, North Carolina 28273

Re: K171872
Trade/Device Name: P50 Series Dental Operative Unit and Accessories
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit And Accessories
Regulatory Class: Class I
Product Code: EIA
Dated: March 26, 2018
Received: March 27, 2018

Dear Frank Ray:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

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

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)*

K171872

Device Name
P50 series Dental Operative Units and Accessories

Indications for Use *(Describe)*

The Pelton & Crane P50 series Dental Operative Units and Accessories are intended to supply power to and serve as a base for other dental devices and accessories by providing air, water, vacuum and low voltage electrical power to dental instruments and dental handpieces. The Pelton & Crane P50 series Dental Operative Units and Accessories are designed for use by a trained professional in the field of dentistry.

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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K171872

Section V – 510(k) Summary
for
P50 series
Dental Operative Unit and Accessories

1. Submitter Information:

Pelton & Crane
11727 Fruehauf Drive
Charlotte, NC 28273

Contact Person: Frank Ray
Telephone Number: (704) 587-7227
Fax Number: (704) 587-7250

Date Prepared: March 26, 2018

2. Device Name:

- Proprietary Name: P50 series
- Manufacturer: Pelton & Crane
- Common Name: Dental Treatment Unit and Accessories
- Classification Name: Unit, Operative Dental
- CFR Number: 872.6640
- Device Class: I
- Product Code: EIA

3. Predicate Device:

- Proprietary Name: ESTETICA - (K161488)
- Manufacturer: Kaltenbach & Voigt GMBH
- Common Name: Dental Treatment Unit and Accessories
- Classification Name: Unit, Operative Dental
- CFR Number: 872.6640
- Device Class: I
- Product Code: EIA

Reference Device #1:

- Proprietary Name: Spirit - (K143696)
- Manufacturer: Pelton & Crane
- Common Name: Dental Delivery Unit
- Classification Name: Unit, Operative Dental
- CFR Number: 872.6640
- Device Class: I
- Product Code: EIA

Reference Device #2:

- Proprietary Name: ELECTROmatic - (K163317)
- Manufacturer: Kaltenbach & Voigt GMBH
- Common Name: Dental Handpiece and Accessories
- Classification Name: Dental Handpiece and Accessories
- CFR Number: 872.4200
- Device Class: I
- Product Code: EBW

4. Description of Device:

The P50 series Dental Operative Unit and Accessories serves as a base that includes components to deliver air, water, electrical power, and vacuum to dental handpieces, instruments, and accessories. The controls are contained in a Doctor's Unit, an Assistant's Unit, and a Cuspidor. Additional parts include mount arms, patient dental chair, foot control, and a junction box that houses a power supply and air/water regulators. The unit may also include a dental operating light and a monitor. Various handpieces, instruments, and accessories can be added to the P50 series Dental Operative Unit which Pelton & Crane does not manufacture but does provide a means to connect them to the P50 series Dental Operative Units. These include, but not limited to, pneumatic handpieces, electric motors with handpieces, scalers, intra-oral cameras, curing lights, air/water syringes, SE and HVE vacuum instruments. Water quality is maintained automatically by the preprogramed cleaning functions for the water lines, cuspidor spouts, and instrument hoses including motors and syringes. Instructions are provided for waterline treatment and suction cleaning agents. Water supply is available by either the municipal water supply or a self-contained water bottle.

Per the Guidance for Industry and FDA Staff; Bundling Multiple Devices or Multiple Indications in a Single Submission, dated June 22, 2007, Pelton & Crane is bundling the P50 series Dental Operative Unit and Accessories models listed below as the models do not differ significantly in purpose, design, materials, energy source, function or any other feature related to substantial equivalence. The device description and intended use are identical for all models listed below. The differences between the models and mounting configurations are cosmetic in nature such as mount arms, upholsteries, etc. All critical components within the P50 series Dental Operative Units and Accessories are common.

The P50 series Dental Operative Units and Accessories are available in the following models in table 5.1 which are offered in various mounting configurations. The various mounting configurations for the P50 series Dental Operative Units and Accessories are illustrated within the use and care manuals.

Table 5.1

Series	Model	Description
P50	P50E	Ellipse Mounted Delivery System
P50	P50P	Post Mounted Unit (PMU) Delivery System
P50	P50S	Side Mounted Delivery System

The designation letters listed at the end of each model represents the style of delivery as identified below.

- E = Ellipse Mounted: The dental unit is mounted to the dental chair and can swing/rotate to the left or right side of the dental chair for use.
- P = Post Mounted: The dental unit is mounted to a utility center which is attached to the side of a dental chair.

- S = Side Mounted: The dental unit is mounted to a cabinet or wall beside the dental chair.

Accessories:

Optional accessories (devices) that are integrated/attached to the P50 series Dental Operative Unit and Accessories have already been cleared by the FDA and have been tested as part of the P50 series Dental Operative Unit and Accessories Electrical and Safety / EMC (Section 17) and Performance Bench Testing (Section 18). Also, Pelton & Crane has quality system processes implemented for risk assessment for devices manufactured in compliance with ISO 14971:2007 as referenced in section 9 (Declarations of Conformity and Summary Reports). This includes the P50 series Dental Operative Unit and Accessories with attached/integrated Devices / Accessories listed below in Table 5.2. The Risk Management File was reviewed by our test house Intertek as part of obtaining 60601-1 certification.

As described in section 15 (Sterilization and Shelf Life), the optional devices that are integrated / attached to the P50 series Dental Operative Unit and Accessories may require sterilization and/or disinfection per their own manuals as they are provided non-sterile and are reusable. The sterilization/disinfection manuals for all Devices/Accessories listed in Table 5.2 below will be supplied with the P50 series Dental Operative Unit and Accessories.

Please note: The Quick Clean air/water syringe, Three-Function Handpiece (air/water syringe), Turbines, MULTIflex couplings, and SONICflex (ultrasonic scaler) listed in table 5.2 below are non-electrical devices.

Table 5.2

Device / Accessory	Manufacturer	Product Code	510(k) Clearance	Integrated / Attached	Mechanism of Integration
INTRA LUX KL 703 LED (motor)*	Kaltenbach & Voigt GmbH	EBW	FDA cleared under K103027 and listed as a predicate Accessory in K161488.	Attached	N/A
INTRA LUX S600 LED (motor)	Kaltenbach & Voigt GmbH	EBW	FDA cleared under K140308 and listed as a predicate Accessory in K161488.	Attached	N/A
Quick Clean air/water syringe**	DCI International	ECB	Class I, exempt under 21 CFR 872.4565 and listed as a Pelton & Crane Accessory in K143696.	Attached	N/A
Three-Function Handpiece (air/water syringe)**	Kaltenbach & Voigt GmbH	ECB	Class I, exempt under 21 CFR 872.4565 and listed as a predicate Accessory in K161488.	Attached	N/A
Turbines	Kaltenbach & Voigt GmbH	EFB	FDA cleared under K073478, K130560 and listed as a predicate Accessory in K161488.	Attached	N/A
Eletrical handpieces	Kaltenbach & Voigt GmbH	EFA EFB	FDA cleared under K073478, K143465 and listed as a predicate Accessory in K161488.	Attached	N/A
MULTIflex couplings	Kaltenbach & Voigt GmbH	EFB	FDA cleared under K073478, K130560 and listed as a predicate Accessory in K161488.	Attached	N/A
SONICflex (ultrasonic scaler)	Kaltenbach & Voigt GmbH	ELC	FDA cleared under K080089 and listed as a predicate Accessory in K161488.	Attached	N/A

Cavitron G139 Scaler***	DENTSPLY International	ELC	FDA cleared under K052334 and linked to Pelton & Crane Accessory in K143696	Integrated	Factory installed only
PiezoLED (electrical scaler)****	E.M.S. Electro Medical Systems	ELC	FDA cleared under K093000, K132443, K140990 and listed as a predicate Accessory in K161488.	Integrated	Factory installed only
Satelec Mini LED (curing light)	Satelec	EBZ	FDA cleared under K032465, K040808 and listed as a predicate Accessory in K161488.	Attached	N/A
DIAGNOcam 2170 (Intraoral Camera)	Kaltenbach & Voigt GmbH	NTK	FDA cleared under K123402 and listed as a predicate Accessory in K161488.	Attached	N/A
Helios 3000 LED dental light*****	Pelton & Crane	EAZ	Class I, exempt under 21 CFR 872.4630	Attached	N/A
Helios 1800 LED dental light*****	Pelton & Crane	EAZ	Class I, exempt under 21 CFR 872.4630	Attached	N/A

* Kaltenbach & Voit GmbH *informed Pelton & Crane that their INTRA LUX KL 703 LED (motor) is linked to 510(k) number K103027 (Model KL 702) and they have quality system records to support this.*
***The syringe is 510(k) exempt, patient contacting, and can be sterilized/disinfected per the Care Instructions.*
**** DENTSPLY International informed Pelton & Crane that their Cavitron G139 Scaler is linked to 510(k) number K052334 (Model G131) and it is their OEM Scaler Dealer Kit which is for integration into dental operative units and they have quality system records to support this.*
***** E.M.S. Electro Medical Systems 510(k) K140990 is designed to integrate into a dental chair (dental unit).*
****** Pelton & Crane Helios dental lights are made to attach to a dental chair. There are no patient contacting parts.*

Principle of Operation / Mechanism of Action:

The P50 series Dental Operative Unit and Accessories is designed to bring a patient into an ergonomic and comfortable position to perform dental treatment procedures. For this purpose, the patient chair can be brought into an appropriate position, either by activating the chair positioning push buttons or by recalled programmed positions set by the user. The dental chairs double articulating headrest is manually adjusted for patient positioning by pushing the quick release button on the backside of the headrest as well as adjusting the height via the slide bar. The treatment is performed by the instruments placed in the designated instrument holders. The required parameters (e.g. power, torque, speed, cooling media) can be adjusted via a panel / touch panel or recalled from settings programmed by the user beforehand. After taking an instrument from its respective holder, it can be activated via the foot control. A tray is provided to place dental hand instruments and materials required during treatment.

The delivery head is mounted to an arm mechanism for support and positioning of the delivery head around the patient. The types of mounting configurations include a chair, utility, cabinet, or wall as illustrated within the Instructions for Use manual. A junction box or utility center provides housing for connections to the facility air, water, vacuum, and power sources, regulators for air and water, and solenoid valves for integrated accessories. Regulated air and water, source vacuum, and power tubing and cables are routed through the mounting arms to the delivery head where the utilities are distributed to the individual dental instruments with a handpiece control system contained in the delivery head.

To remove fluids and particles deriving from the oral cavity during treatment, suction hoses with attached instruments are provided on the assistant element. Selecting the suction instruments, the vacuum is activated by the Thumb Lever. A cuspidor bowl is available for patient rinse. Also, air and water syringes are not activated when removing from the instrument holder but rather

by the air/water regulators and the solenoid valve. Air and water flow is manually opened and closed with button actuated valves integrated into the syringe body.

An operating light providing illumination to the oral cavity can be switched on via the panel / touch screen or can be operated manually. Most chair and instrument related functions can be activated hands-free via foot control. The panel / touch screen style user interface applies context-sensitivity; i.e. according to the actual operational state, user-defined buttons and functions are displayed and provided for use. Prescribed procedures and supporting components apply to facilitate infection control and maintaining water quality, such as automated instrument hose purge. The automated purge opens all valves in the delivery head to run water and cleaning solution from the water bottle through all instrument lines for the duration specified by the program selected by the user. The program is activated with the touchscreen by the user. Instructions are also provided for waterline treatment and suction cleaning agents. Water supply is available by either the municipal water supply or a self-contained water bottle.

As an option the P50 series Dental Operative Unit and Accessories can be equipped with an endodontic and / or surgery function. The endodontic function has an electronic torque limitation with variable torque modes (auto reverse, auto reverse forward and torque control only). The surgery function has different program steps according to the implantation activities (pilot drilling, form drilling, tapping, placing implant, setting a closure cap, marking and free use).

Also a peristaltic pump and a NaCl bottle holder can be attached to the dentist element. The peristaltic pump prepares a sterile saline solution instead of spray water for cooling. This system connects as a "closed system" to the P50 series Dental Operative Unit and Accessories to ensure full sterility.

5. Indications for Use:

The Pelton & Crane P50 series Dental Operative Units and Accessories are intended to supply power to and serve as a base for other dental devices and accessories by providing air, water, vacuum and low voltage electrical power to dental instruments and dental handpieces. The Pelton & Crane P50 series Dental Operative Units and Accessories are designed for use by a trained professional in the field of dentistry.

6. Description of Substantial Equivalence: Technological Characteristics:

The P50 series Dental Operative Units and Accessories function in a manner similar to and are intended for the same indications for use as the predicate device ESTETICA Dental Treatment Unit and Accessories (K161488) marketed by Kaltenbach & Voigt GmbH. There are numerous identical technological characteristics such as handpiece positions, quantity/type of electric motors, user interfaces, syringes, turbines, control of coolant, scalers, intraoral camera, curing lights, endodontic, USB interface with Dentist Element, suction, dental chairs with lift and recline, headrests, arm rests, footswitches, programable positions, water connections to municipal water or water bottle, cuspidor bowls, waterline treatment, automated instrument cleaning, water/suction hose treatment, purge, foot controls, PC interface and LED dental lights, waterline treatment process and solution (KaVo OXYGENAL 6), automated instrument cleaning, purge function, preprogramed cleaning functions, daily cleaning process, weekly cleaning process, and a hygiene center.

However, there are different technological characteristics such as electrical power ranges as well as the predicate device has an optional multi-functional syringe with internal heater for water and light, x-ray viewer, curing light option and USB interface on assistant's unit, dental

chair lift capacity, armrest movement, traverse chair movement, adjustable cuspidor, amalgam separator, water unit heater and automated vs manual suction hose cleaning, monitor mount and optional wireless foot control. Furthermore, the proposed device offers a Cavitron Scaler option in addition to the PiezoLED with light and the SONICflex scalers options listed by both the proposed and predicate devices.

These different technological characteristics do not raise new concerns of substantial equivalence. The comparison table below (table 5.3) for the P50 series Dental Operative Units and Accessories (proposed device) and the ESTETICA Dental Treatment Unit and Accessories (predicate device) are substantially equivalent in terms of indication for use, technology and performance specifications as the few differences between the proposed device and the predicate device do not impact substantial equivalence. The performance testing results provided in this submission supports that the proposed device performs as well as the predicate devices for its intended use. Hence, the device is deemed to be substantially equivalent to the ESTETICA Dental Treatment Unit and Accessories (K161488).

Please note the two reference devices (Spirit - K143696 marketed by Pelton & Crane and ELECTROmatic - K163317 marketed by Kaltenbach and Voigt GmbH) are referenced in Biocompatibility section as they contain numerous identical patient contacting parts."

Table 5.3

Descriptive Information	**Proposed Device** **P50 series Dental Operative Unit and Accessories**	**Predicate Device** **ESTETICA Dental Treatment Unit and Accessories**
Intended Use / Indications for Use	The Pelton & Crane P50 series Dental Operative Units and Accessories are intended to supply power to and serve as a base for other dental devices and accessories by providing air, water, vacuum and low voltage electrical power to dental instruments and dental handpieces. The Pelton & Crane P50 series Dental Operative Units and Accessories are designed for use by a trained professional in the field of dentistry.	The ESTETICA Dental Treatment Unit and Accessories are intended to supply power to and serve as a base for other dental devices and accessories by providing air, water, vacuum and low voltage electrical power to dental instruments and dental handpieces. The ESTETICA Dental Treatment Unit and Accessories are designed for use by a trained professional in the field of general dentistry.
Regulation Number	21 CFR 872.6640	21 CFR 872.6640
Regulation Title	Dental operative unit and accessories	Dental operative unit and accessories
Regulation Class	I	I
Product Code	EIA	EIA
Power and Utility Supply	115V/230V AC electrical supply, compressed air and water	100V/240V AC electrical supply, compressed air and water
Protection Class	Class 1 Equipment	Class 1 Equipment
Applied Parts	Type B	Type B
Control of Air and Water	Uses pneumatically controlled valves to Water control the flow of air and water. On/off and intensity controlled by foot pedal.	Uses pneumatically controlled valves to Water control the flow of air and water. On/off and intensity controlled by foot pedal.

Dentist Element	Positions	6 handpiece positions + 1 additional	6 handpiece positions + 1 additional
	Max. Motors	Up to 4 motors (electrical motors with and without light)	Up to 4 motors (electrical motors with and without light)
	Electric Motors	INTRA LUX KL 703 LED	INTRA LUX KL 703 LED
		INTRA LUX S600 LED	INTRA LUX S600 LED
	User Interface	EasyTouch Display, color	ESTETICA E70/E80 Vision: EasyTouch Display, color ESTETICA E50 Life: Display, with several keys (foil) and Status LED
		Hands free operation via foot control	Hands free operation via foot controller.
	Syringe	3 Functional syringe without heater and light or Quick Clean air/water syringe	Multifunctional syringe with internal heater for water and light or 3 Functional syringe without heater and light
	Turbines	Turbines with light	Turbines with light
		MULTIflex couplings	MULTIflex couplings
	Control of Coolant	Water pressure controlled by the unit	Water pressure controlled by the unit
		Air pressure controlled by the unit	Air pressure controlled by the unit
	Scaler	PiezoLED with light SONICflex CAVITRON G139	PiezoLED with light SONICflex
	Intraoral Camera	DIAGNOcam 2170	DIAGNOcam 2170
	Curing Light	Satelec Mini LED	Satelec Mini LED
	X-ray Viewer	N/A	Panorama X-ray image viewer or small X-ray viewer
	Endodontic	Implantology functions	Implantology functions
		Endodontic treatment functions	Endodontic treatment functions
		Adapted pump for saline solution	Adapted pump for saline solution
	Interfaces	USB Interface	USB Interface
Assistant Element	Positions	Up to 3 suction positions, 1 handpiece position (syringe)	2/3 suction positions, 2 handpiece positions (syringe and curing light)
	User Interface	Touch pad (foil) with several keys and status LEDs	Touch pad (foil) with several keys and status LEDs
	Syringe	3 Functional syringe without heater and light or Quick Clean air/water syringe	Multifunctional syringe with internal heater for water and light or 3 Functional syringe without heater and light
	Curing Light	Satelec Mini LED	Satelec Mini LED
	Suction	Suction devices	Suction devices
		Saliva ejector	Saliva ejector
		HVE (High volume evacuator)	HVE (High volume evacuator)
		Surgical suction devices	Surgical suction devices
	Interfaces	No USB interface	USB interface

Chair	Patient load	SP30 Chair – 450 lbs SP18 Chair – 350 lbs SP17 Chair – 350 lbs	ESTETICA E70/E80 Vision: 396 lbs ESTETICA E50 Life: 407 lbs (Standard Chair) ESTETICA E50 Life: 297 lbs (Compact Chair)
	Headrest	Manually operated	Manually operated or motorized headrest
	Upholstery	Naugasoft or Ultraleather upholstery	Skai upholstery
	Armrest	Armrest, retractable, rotate	Armrest, retractable
	User interface	Foot-switch and touchpad	Foot-switch
	Movement	Synchronized Backrest and seat movements	Synchronized Backrest and seat movements
		User programmable positions	User programmable positions
		Backrest hydraulic driven	Backrest motor driven
		N / A	ESTETICA E80 Vision: Horizontal movement, seating bench lifting
		Seat and seat inclination hydraulic driven	Seat and seat inclination motor driven
Water unit	Cuspidor bowl	Fixed bowl optional	Manually adjustable or Motor driven cuspidor bowl
	Amalgam separator	N / A	Amalgam separator
	Water	Connection to municipal water or Self-contained water bottle	Connection to municipal water with safety separation via "air gap". Self-contained Water bottle option for E50.
	Heating	No heater	Water heater
	Water / Suction Hose treatment	Waterline Treatment solution	Waterline Treatment solution
		Automated instrument cleaning	Automated instrument cleaning
		Manual suction hose cleaning w/suction line cleaner	Automated suction hose cleaning w/suction line cleaner
	Water treatment	Waterline Treatment solution	Waterline Treatment solution
	Purge	Purge function	Purge function
	Pre-programmed waterline cleaning functions	Automatic for water lines, cuspidor, spouts, and instrument hoses including motors and syringes	Automatic for water lines, cuspidor, spouts, and instrument hoses including motors and syringes
	Daily Cleaning	Automated instrument flush with water before start up and after down times. Recommend 2 minutes per instrument	Automated instrument flush with water before start up and after down times. Recommend 2 minutes per instrument
		Automatic after patient cleaning of water and drainage system via fresh water and cleaning solution if used. Recommended 20 seconds	Automatic after patient cleaning of water and drainage system via fresh water and cleaning solution if used. Recommended 20 seconds
	Weekly Cleaning	Automated flush with cleaning solution	Automated flush with cleaning solution
		Water Cleaner: KaVo OXYGENAL 6	Water Cleaner: KaVo OXYGENAL 6
	Water Line Treatment	Recommended 45 minutes cleaning time to complete.	Recommended 45 minutes cleaning time to complete.
	Recommended disinfectors	In accordance to EN ISO 15883-1 using alkaline cleaning agents	In accordance to ISO 15883-1 using alkaline cleaning agents
	Hygiene Center	External holder for hoses and syringes during automated waterline cleaning	External holder for hoses and syringes during automated waterline cleaning
General	Operating Light	Helios dental light 3000 - LED Helios dental light 1800 - LED	LEDview - LED
	Monitor	N / A	19" or 22" monitor on the light support frame

	Foot Control	Standard DCI foot switch with chair foot control	Wireless Foot control available
		Electronic foot control	Electronic foot control
	PC Interface	Yes	Yes

Non-Clinical Test Data:

Performance bench testing according to international standards for dental operative units has been conducted to determine conformance in regards to:

- Biocompatibility has been completed for the applicable components. Please note, the two reference devices (Spirit - K143696 marketed by Pelton & Crane and ELECTROmatic - K163317 marketed by Kaltenbach & Voigt GmbH) are referenced in Biocompatibility as they contain numerous identical patient contacting parts.
- Software documentation for moderate level of concern per the FDA Guidance Document for Software Contained in Medical Devices.
- Comparative performance testing of the functions of the integrated accessories as compared to the cleared stand-a-lone device.

Furthermore, the performance of the P50 series Dental Operative Unit and Accessories has been verified utilizing the following standards:

- AAMI ES60601-1:2005 +AC1; A2, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (R2012).
- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007), Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2 Edition 3: 2007-03, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- ISO 10993-1 Fourth edition 2009-10-15, biological evaluation of medical devices - part 1: evaluation and testing within a risk management process [including: technical corrigendum 1 (2010)].
- ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry (Including: Amendment 1 (2013)).
- CAN/CSA-C22.2 No. 60601-1: 08(R2013) Issued: 2011/06/01 Medical Electrical Equipment - Part 1: General Req. for Basic Safety & Essential Perf.; Cor. 2: 2011
- IEC 80601-2-60 Edition 1.0 2012-02, medical electrical equipment - part 2-60: particular requirements for the basic safety and essential performance of dental equipment
- IEC 62304 Edition 1.1 2015-06, medical device software - software life cycle processes.
- ISO 9168 Third edition 2009-07-15 Dentistry - Hose connectors for air driven dental handpieces.
- ISO 14457 First edition 2012-09-15 – Dentistry – Handpieces and motors.
- ISO 7494-2 Second edition 2015-04-01, dentistry - dental units - part 2: air, water, suction and waste water system.
- ISO 7494-1 Second edition 2011-08-15 - Dentistry - Dental units - Part 1: General requirements and test methods.
- ISO 14971 Second Edition 2007-03-01, Medical Devices - Application of risk management to medical devices.

Hence the P50 series Dental Operative Unit and Accessories demonstrates substantial equivalence.

Clinical Performance Data:

Clinical data is not needed to characterize performance and establish substantial equivalence. The non-clinical test data characterize all performance aspects of the device based on well-established scientific and engineering principles. Clinical testing has not been conducted on this product.

Conclusion as to Substantial Equivalence:

Based on a comparison of intended use, indications, technological characteristics, principle of operation, features and performance data, the P50 series Dental Operative Unit and Accessories are deemed to be substantially equivalent to the predicate device.