Forest Dental Products, Inc.
Erin-Kate Barton
6200 NE Cherry Drive
Hillsboro, Oregon 97124

August 17, 2018

Re: K173608
Trade/Device Name: Forest Dental Unit
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit And Accessories
Regulatory Class: Class I
Product Code: EIA
Dated: July 18, 2018
Received: July 20, 2018

Dear Erin-Kate Barton:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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

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

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)*
K173608

Device Name
Forst Dental Unit

Indications for Use *(Describe)*
The Forest Dental Units are intended to serve as a base for ancillary dental devices and accessories by providing air, water, vacuum, and low voltage electrical power to hand-held dental instruments. The Forest Dental Units are intended for use by dental practitioners to provide diagnostic and therapeutic treatment to dental patients in a clinical environment.

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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5.1 510(k) Summary

Traditional 510(k) Summary for Forest Dental Operative Unit and Accessories

5.1 Submitter

Forest Dental Products, Inc.
6200 NE Cherry Drive
Hillsboro, OR 97124

Contact Person: Erin-Kate Barton
Telephone Number: 971-327-9024
Facsimile Number: 503-693-9715
E-mail address: ekbarton@forestdental.com

Date Prepared: July 18, 2018

5.2 Device Name

Proprietary Name: Forest Dental Unit
Common Name: Dental Delivery Unit
Classification Name: Dental Operative Unit and Accessories
CFR Number: 872.6640
Device Class: I
Product Code: EIA

5.3 Primary Predicate Device

Proprietary Name: SPIRIT – K143696
Common Name: Dental Delivery Unit
Classification Name: Dental Operative Unit and Accessories
CFR Number: 872.6640
Device Class: I
Product Code: EIA

5.4 Device Description

The Forest Dental Unit serves as a base for ancillary dental devices and accessories by providing air, water, vacuum, and low voltage electrical power to hand-held dental instruments. The controls are contained in a Doctor's Unit, Assistant's Instrumentation Unit, Duo Unit (both Doctor's and Assistant's Control) and Cuspidor and are configured in a variety of mounts. Additional accessory items include a pneumatic unit foot control, utility center (aka junction box) that houses a power supply and air/water regulators, hoses, trays, and mounting assemblies. The dental unit is supplied air and water from the utility connections through air/water regulators via the umbilical chase. The dental unit is supplied

SELV-24VAC from the output of the power supply, also routed through the umbilical chase and terminated on an internal terminal strip.

Various ancillary dental devices can be connected to the Forest Dental Unit which are attached by means of industry standard ISO connections. These ancillary devices include, but are not limited to, pneumatic handpieces, air/water syringes, SE and HVE vacuum instruments, electric micromotors, intra-oral cameras, scalers and curing lights. While Forest does not manufacture pneumatic or electric handpieces, scalers, intra-oral cameras or curing lights, it supplies ancillary devices in partnership with other manufacturers. These include Dentsply Cavitron Scaler (K150535), Satelec Ultasonic Scaler (K132267), and Bien-Air Electric Micromotor Handpiece (K042759). Other ancillary devices described above may be supplied to the end-user by authorized dental dealers.

Per the Guidance for Industry and FDA Staff, Bundling Multiple Devices or Multiple Indications in a Single Submission, dated June 22, 2007, Forest is bundling the Forest Dental Unit models listed in Table 5.1 below. The models do not differ significantly in purpose (intended use), design, function, materials, energy source or any feature related to substantial equivalence. The device description and intended use are the same for all configurations of the models listed in Table 5.1.

The differences between the models in Table 5.1 include various mounting arms for positioning relative to the dental practitioner based on ergonomic preferences and do not influence device performance. The various models also represent differences in size/shape of the delivery head (aka control head) and pneumatic handpiece control block (pinch versus diaphragm style). The Forest models also provide various selling price points based on accessory features. All functional and critical components of the different configurations are common.

Dental Operative Units are an established, commoditized device type provided by numerous manufacturers. While specialty features exist (for example to offer greater portability or integration of ancillary controls), most dental operative units offer the same technology, connections, user interfaces and mounting options as provided by Forest Dental. Consequently, the Forest Dental operative units may be considered largely comparable or equivalent to most conventional systems that utilize cart, chair, wall or cabinet mounts and that provide a traditional, continental, pivot, or rear/side delivery style to the operator.

The different dental unit configurations are described in the Installation Guides and Operator’s Guides (Instructions for Use) for each model. The table below identifies each model and description:

Table 5.1 Forest Dental Unit – Model Listing

Model #	Description
1095	ASSISTANT'S INSTRUMENTATION W/INTERNAL UMBILICAL, REAR PIVOT CHAIR MOUNT
1284	ASSISTANT'S REAR BENEATH COUNTER SHELF MOUNT (CLEAN WATER, WATER SHUT-OFF AND REGULATOR NOT INCLUDED)
1590	DELUXE CUSPIDOR W/ASSISTANT'S INSTRUMENTATION & INTERNAL UMBILICAL, REAR PIVOT CHAIR MOUNT
1637	BASIC CUSPIDOR W/ASSISTANT'S INSTRUMENTATION & EXTERNAL UMBILICAL, POST MOUNT
2184	DUO UNIT, LEFT/RIGHT, VERTICAL MOUNT PANEL CONTROL (WORK SURFACE NOT INCLUDED)
2400	DR'S SIDE BENEATH COUNTER MOUNT STANDARD IC CONTROL HEAD
2500	DR'S PANEL MOUNT, COMPACT CONTROL, 3-HANDPIECE AUTOMATIC
2520	DR'S PANEL MOUNT, COMPACT CONTROL, 3-HANDPIECE AUTOMATIC
3230	DR'S SIDE WALL/VERTICAL MOUNT W/RIGID/FLEX ARM W/STANDARD IC CONTROL HEAD
3235	DR'S SIDE CABINET/VERTICAL MOUNT W/RIGID/FLEX ARM W/STANDARD IC CONTROL HEAD
5350	IC ECONOMY DOCTOR'S MOBILE CART
5355	IC ECONOMY DUO MOBILE CART
5386	ASSISTANT'S SWING/MOBILE CART W/VACUUM ARM, ASST'S INSTRUMENTATION & LAMINATE WORK SURFACE
5886	DUO SWING/MOBILE CART W/STANDARD IC CONTROL & LAMINATE WORK SURFACE
1091INT-DURR	ASST'S INSTRUMENTATION, W/ DURR VACUUM, REAR
1092INT-DURR	ASST'S INSTRUMENTATION, W/ DURR VACUUM, FIXED
1095INT	ASST'S INSTRUMENTATION, REAR PIVOT MOUNT
1286MCC	ASST'S INSTRUMENTATION, HORIZONTAL MOUNT W/LINK
1400-412	BDS-0050 REAR ASST'S SWING MOUNT, BEL-50
1500PI	REAR PIVOT MOUNT DUO UNIT W/INTERNAL UMBILICAL & STANDARD IC CONTROL HEAD
1578INT-DURR	FIXED CHAIR MOUNT DELUXE CUSPIDOR W/DURR
1637FE	BASIC CUSPIDOR W/ASSISTANT'S INSTRUMENTATION & EXTERNAL UMBILICAL, POST MOUNT, W/WATER REGULATOR & MASTER SHUT-OFF
2001INT	HEAD ASSY, IC STANDARD W/FLEX ARM
2002INT	HEAD ASSY, IC CONTOURED W/FLEX ARM
2003INT	HEAD ASSY, EURO W/FLEX ARM
2501MCC	COMPACT CONTROL, PANEL MOUNT, 3 HP, MCC
2502MCC	COMPACT CONTROL, PANEL MOUNT, 3 HP, MCC
2520MCC	COMPACT CONTROL, PANEL MOUNT, 2 HP AUTOMATIC
2521MCC	COMPACT CONTROL, PANEL MOUNT, 2 HP AUTOMATIC
2522MCC	COMPACT CONTROL, PANEL MOUNT, 2 HP AUTOMATIC
3486BC	ASSISTANT'S REAR MOUNT BENEATH COUNTER SIDE DELIVERY W/LAMINATE TOP

Model #	Description
3486UC	ASSISTANT'S REAR MOUNT UNDER CABINET SIDE DELIVERY W/LAMINATE TOP
3486WM	ASSISTANT'S REAR WALL MOUNT SIDE DELIVERY W/LAMINATE TOP
4001-225	BDS-2561 LEFT RIGHT DUO UNIT, BELMONT
4001-226	BDS-2563 LEFT RIGHT ASSISTANTS UNIT, BELMONT
4195FE	FIXED CHAIR MOUNT DR'S UNIT WITHOUT SIDEBOX W/EXTERNAL UMBILICAL & VALUE CONTROL HEAD
4195PI	PIVOT CHAIR MOUNT DR'S UNIT W/INTERNAL UMBILICAL & VALUE CONTROL HEAD
4195SE	FIXED CHAIR MOUNT DUO UNIT W/SIDEBOX, EXTERNAL UMBILICAL & VALUE CONTROL HEAD
4195SI	FIXED CHAIR MOUNT DUO UNIT W/SIDEBOX, INTERNAL UMBILICAL & VALUE CONTROL HEAD
4485FE	FIXED CHAIR MOUNT DR'S UNIT WITHOUT SIDEBOX W/EXTERNAL UMBILICAL & STANDARD IC CONTROL HEAD
4485PI	PIVOT CHAIR MOUNT DR'S UNIT W/INTERNAL UMBILICAL & STANDARD IC CONTROL HEAD
4485SE	FIXED CHAIR MOUNT DUO UNIT W/SIDEBOX, EXTERNAL UMBILICAL & STANDARD IC CONTROL HEAD
4485SI	FIXED CHAIR MOUNT DUO UNIT W/SIDEBOX, INTERNAL UMBILICAL & STANDARD IC CONTROL HEAD
4987FE	FIXED CHAIR MOUNT DR'S UNIT WITHOUT SIDEBOX W/EXTERNAL UMBILCAL & EURO CONTROL HEAD
4987PI	PIVOT CHAIR MOUNT DR'S UNIT W/INTERNAL UMBILICAL & EURO CONTROL HEAD
4987SE	FIXED CHAIR MOUNT DUO UNIT W/SIDEBOX, EXTERNAL UMBILICAL & EURO CONTROL HEAD
4987SI	FIXED CHAIR MOUNT DUO UNIT W/SIDEBOX, INTERNAL UMBILICAL & EURO CONTROL HEAD
7000INT	DUO SWING DELIVERY SYSTEM 7000
7000INT-DURR	DUO SWING DELIVERY SYSTEM 7000 W/ DURR VACUUM
7010BC	DUO SYSTEM, REAR MOUNT, BENEATH COUNTER SIDE DELIVERY W/SOLID SURFACE TOP
7010MC	DUO MOBILE CART W/ SOLID SURFACE TOP
7010UC	DUO SYSTEM, REAR MOUNT, UNDER CABINET FLOOR MOUNT SIDE DELIVERY W/SOLID SURFACE TOP
7010WM	DUO SYSTEM, REAR MOUNT, WALL MOUNT SIDE DELIVERY W/SOLID SURFACE TOP
7020PRO-BC	DUO DELIVERY PRO 7000 SERIES, BENEATH COUNTER
7020PRO-MC	DUO DELIVERY PRO 7000 SERIES, MOBILE CART
7020PRO-UC	DUO DELIVERY PRO 7000 SERIES, UNDER CABINET FLOOR MOUNT
7020PRO-WM	DUO DELIVERY PRO 7000 SERIES, WALL MOUNT
7021PRO-BC	DUO DELIVERY PRO BASE MODEL, 7000 SERIES, BENEATH COUNTER
7021PRO-MC	DUO DELIVERY PRO BASE MODEL, 7000 SERIES, MOBILE CART
7021PRO-UC	DUO DELIVERY PRO BASE MODEL, 7000 SERIES, UNDER CABINET FLOOR MOUNT
7021PRO-WM	DUO DELIVERY PRO BASE MODEL, 7000 SERIES, WALL MOUNT

Model #	Description
7022PRO-BC	ASST'S DELIVERY PRO 7000 SERIES, BENEATH COUNTER
7022PRO-MC	ASST'S DELIVERY PRO 7000 SERIES, MOBILE CART
7022PRO-UC	ASST'S DELIVERY PRO 7000 SERIES, UNDER CABINET FLOOR MOUNT
7022PRO-WM	ASST'S DELIVERY PRO 7000 SERIES, WALL MOUNT
7023PRO-BC	ASST'S DELIVERY PRO BASE MODEL, 7000 SERIES, BENEATH COUNTER
7023PRO-MC	ASST'S DELIVERY PRO BASE MODEL, 7000 SERIES, MOBILE CART
7023PRO-UC	ASST'S DELIVERY PRO BASE MODEL, 7000 SERIES, UNDER CABINET FLOOR MOUNT
7023PRO-WM	ASST'S DELIVERY PRO BASE MODEL, 7000 SERIES, WALL MOUNT
MT600BS	DR'S BENEATH SHELF MOUNT, MT COMPACT CONTROL, 3-HANDPIECE AUTOMATIC
MT600TS	DR'S TOP SHELF MOUNT, MT COMPACT CONTROL, 3-HANDPIECE AUTOMATIC
MT610BS	DR'S BENEATH SHELF MOUNT, MT COMPACT CONTROL, 2-HANDPIECE AUTOMATIC
MT610TS	DR'S TOP SHELF MOUNT, MT COMPACT CONTROL, 2-HANDPIECE AUTOMATIC

Principle of Operation:

The dental unit (delivery system, control head) is mounted to an articulated arm mechanism for support and positioning of the dental unit relative to the patient's head. The types of mounting configurations include chair, cabinet, wall, and cart as described in the product labeling. The mounting configuration determines the location of the utility center which provides the housing and necessary connections for pressurized air, vacuum, water and electrical power. Tubing and electrical cables are routed through the umbilical assembly located in the mounting arm of the dental unit and make the connection from the control head to the utilities, or the source of regulated air, water and vacuum source. These utilities are distributed to the individual ancillary devices by the pneumatic system located within the control head.

The pneumatic system that powers the handpiece distributes air and water to the individual devices once they are selected, i.e. removed from their respective holder. Once an individual device is activated, the control block prevents any other handpiece device from becoming active (lock-out). Only one handpiece device can be active at any given time, once a device is returned to the holder it is no longer active. The foot control operates the handpiece using drive air and activates coolant air and water. Individual handpiece drive air and water flow adjustments are controlled by the operator via external control valve knobs attached to the internal control block. For handpieces with pneumatically activated internal lighting capability, the time delay of the output light can be

adjusted after the foot control is released. The control head has a master on-off switch that shuts on/off air and water to the dental unit.

Suction instruments, High-Volume Extractor(HVE) and Saliva Ejector(SE) ancillary devices, are not activated by or operated with the handpiece pneumatic system but each have their own manual valve for activation. These devices operate independently, as part of the vacuum system; they can be used at the same time as a handpiece and air/water syringe.

The air/water dental syringe is also not activated with the handpiece pneumatic system but is manually activated by depressing the water and air button actuated valves on the syringe body. The syringe can be used at the same time as a handpiece and suction instruments. This device operates by delivering air and water through the syringe body and tip into the oral cavity.

Electrically powered ancillary devices can be configured with the dental unit. These include but are not limited to Dentsply Cavitron Scaler (K150535), Satelec Ultasonic Scaler (K132267), and BienAir Electric Micromotor Handpiece (K042759). When configured with one or more of these devices, the ancillary control module is located either in the unit control head or attached underneath the unit control head as described by the ancillary device manufacturer's installation instructions. The SELV-24VAC is supplied to the ancillary control module(s) and the associated handpiece is located on one of the handpiece control holders. Air and water are supplied and routed through the proprietary tubing assembly for the device. The handpieces for these electrically powered ancillary devices are activated by the control block identical to the pneumatic handpieces for active operation lock-out and the handpiece drive air provides a signal for activation of the electric power for operation of the handpiece.

5.5 Indications for Use:

The Forest Dental Units are intended to serve as a base for ancillary dental devices and accessories by providing air, water, vacuum, and low voltage electrical power to hand-held dental instruments. The Forest Dental Units are intended for use by dental practitioners to provide diagnostic and therapeutic treatment to dental patients in a clinical environment.

5.6 Description of Substantial Equivalence

We chose the Pelton & Crane dental operative unit (K143696) to be the **primary predicate** device. Table 5.2 provides a visual and tabular comparison between the Forest Dental unit and predicate unit by Pelton & Crane.

To demonstrate substantial equivalence, three types of comparative analyses were performed:

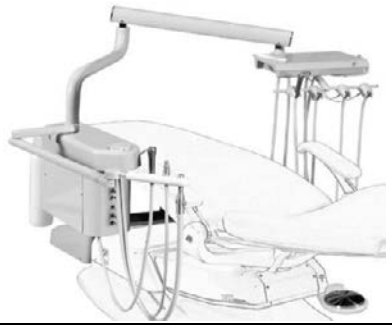
- Detailed predicate device comparisons on electrical, mechanical and environmental specifications. Comparison of key features and functions.
- Clinical Performance Data
- Non-Clinical Performance Data

5.6.1 Technological Characteristics

The Forest Dental Operative Units have the same intended use as previously cleared Spirit Dental Operative Units (K143696) manufactured by Pelton & Crane. Both are compatible with multiple accessory attachments such as optional trays, surfaces, and gravity drain cuspidors and may be installed using a variety of mounting options including direct attachment to the chair. While there are some different technological characteristics of the Spirit (See Table 5.2), these differences do not raise new concerns of substantial equivalence as compared to the predicate device. The performance data and testing of the Forest Dental Units demonstrates that the unit is as substantial in equivalence to the Pelton & Crane Spirit Dental Operative Unit.

Table 5.2

Description of Substantial Equivalence-Comparison Table

Comparison Parameter	Primary Predicate Device Pelton & Crane Spirit 1500 OTP w/Traditional Delivery Dental Operative Unit (K143696)	Forest Dental Operative Unit and Accessories, 4485SI
		
Indications for Use	The Spirit Dental Operative Units 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 hand held dental instruments. The Spirit Dental Operative Units are intended for use by professional dental practitioners in providing treatment to dental patients in a dental operatory.	The Forest Dental Units are intended to serve as a base for ancillary dental devices and accessories by providing air, water, vacuum, and low voltage electrical power to hand-held dental instruments. The Forest Dental Units are intended for use by dental practitioners to provide diagnostic and therapeutic treatment to dental patients in a clinical environment.
Regulation Number	21 CFR 872.6640	Same as Primary Predicate Device
Regulation Title	Dental operative unit and accessories	Same as Primary Predicate Device
Regulation Class	I	Same as Primary Predicate Device
Product Code	EIA	Same as Primary Predicate Device
Device Classifications (Electrical)	Class I, Type B applied part, IPX0, continuous operation	Same as Primary Predicate Device
Utilities and Standards		
Transportation / Storage temperature	-68°F to 122°F	-20°F to 140°F [1]
Relative humidity range	10% to 90%	25% to 90% [1]
Operating temperature range	68°F to 76°F	Same as Primary Predicate Device

Comparison Parameter	Primary Predicate Device Pelton & Crane Spirit 1500 OTP w/Traditional Delivery Dental Operative Unit (K143696)	Forest Dental Operative Unit and Accessories, 4485SI
Air supply pressure range	80-105 psi	Same as Primary Predicate Device
Air/oil separator	Gauze pad	Same as Primary Predicate Device
Water supply pressure range	40-80 psi	Same as Primary Predicate Device
Isolated water bottle system	Optional	Standard Feature [6]
Standards	EN 60601-1-2:2007 Part 1-2 EN 61000-3-2:2006+A1:2009 +A2:2009 Part 3-2 ES 60601 -1 Part 1 ISO 7494-1:2004 ISO 7494-2:2003	Same as Primary Predicate Device, plus IEC 80601-2-60 [8]

User / Service Interface		
Number of user accounts	One	N/A [5]
Setting display	LCD screen	N/A [5]
Screen navigation	Navigation arrows	N/A [5]
Software updates	Via internal 10-pin port	N/A [5]
Error tracking	Available	N/A [5]
Built-in diagnostics	Available	N/A [5]
Hand Held Devices		
Optional ancillary devices	Air/water syringe Saliva ejector HVE Up to 2 micro motors Scaler Camera Curing light Pneumatic motor	Air/water syringe Saliva ejector HVE Up to 2 micro motors [7] Scaler [7] Intra-oral Camera [7] Curing light [7] Pneumatic motor [7]
Ancillary connections	Mechanically attached and supplied utilities	Same as Primary Predicate Device [5,7]
Number of hand piece locations	4-6	4-5 [2]
Hand piece control system	Valve block	Same as Primary Predicate Device
Syringe water flow control	Adjustable	Optional [2]
Syringe air flow control	Adjustable	Optional [2]
Coolant air flow control	Adjustable	Same
Hand piece air and water bypass	Handpiece air and water bypass is not necessary for the Primary Predicate both air and water are pneumatically controlled rather than electronically controlled.	Same as Primary Predicate Device
Number of hand piece presets	Six	N/A [5]
Remote hand piece activation with water toggle	Via foot control	Same as Primary Predicate Device
Positioning		
Delivery unit head positioning	Flex arm	Same as Primary Predicate Device

Flex arm brake release	Mechanically Integrated	Same as Primary Predicate Device
Maximum load on flex arm mounted units	10 lbs [4]	10 lbs [2,4]
Panel Mount	Not offered with Primary Predicate	Dental Unit control head mounted to a dental furniture vertical face. [2]
Additional Features		
Endodontic capability	Offered	Same as Primary Predicate Device
Hand piece flush	Standard feature	Same as Primary Predicate Device
Air/Water quick connect ports	Offered	Same as Primary Predicate Device
Light control	Offered	Not offered [2]
Tray options	One	Same as Primary Predicate Device
Unit configurations for dominant hand	Left/Right	Same as Primary Predicate Device

[1] Forest storage temperature evaluated per ISTA Table 3A, Extreme Cold, Uncontrolled RH and Hot, Humid, then Extreme Heat and Moderate RH. These differences do not affect substantial equivalence as the testing parameters chosen are reasonable and adequate for normal use and transportation conditions.

[2] These differences do not affect substantial equivalence as they are only differences in marketing features between the proposed device and the predicate device.

[4] In the Spirit Dental Operative Unit manuals, it states: "The maximum weight capacity for the control head is 3lbs." However, this only notes the limit of additional weight that can be placed on the control head. When considering the load of the control head itself and included accessories, the maximum load on the flex arm is 10lbs. Forest Dental maximum capacity for the flex arm is 4.5lbs. which is in addition to the weight of the control head.

[5] **User Service / Interface Features:** Number of User Accounts, Setting Display, Screen Navigation, Software Updates, Error Tracking and Built-in Diagnostics. The predicate Spirit dental unit has an integrated LCD panel for control of ancillary devices (i.e. ELECTROtorque TLC, COMFORTronic/COMFORTdrive Handpiece). The Forest system utilizes the display panel/control touchpad provided by the ancillary device manufacturer which is installed on the Forest dental unit's control head holder bar instead of being built-in to the control head. The display panel/control touchpad from the device manufacturer provides the functionality for the number of accounts, setting display, and screen navigation; software updates, error tracking and built-in diagnostics are also controlled by the software of the ancillary device manufacturer. Both the predicate device and Forest dental units are not software controlled. This provides equivalent performance and there are no safety issues introduced between the two types of display/control touchpad setups.

[6] **Isolated Water Bottle System:** Forest considers this feature as a necessary and essential item to include in all standard configurations. This improves the patient safety of our system over the predicate device by providing known quality water for use in general dental procedures.

[7] **Optional Accessories:** Pneumatic handpieces, electric micromotors, cameras, scalers and curing lights are not manufactured by Forest Dental and are installed by the end-user (qualified service technician on behalf of the customer) using the same installation method used by Primary Predicate device manufacturer. As an added service, Forest will configure a Bien-Air micromotor, Satelec scaler or Cavitron scaler into the dental unit. The Primary Predicate offers the same service but with different ancillary brands.

[8] **Standards Compliance:** Performance and safety standards applied specifically to the Forest Dental operative unit include:

EN 60601-1-2:2007 Part 1-2

EN 61000-3-2:2006+A1:2009 +A2:2009 Part 3-2

ISO 7494-1 Second edition 2011-08-15 Dentistry - Dental units - Part 1: General requirements and test methods

ISO 7494-2 Second edition 2015-04-01 Dentistry - Dental units - Part 2: Air, water, suction and waste water

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 ISO 7494-1, ISO 7494-2, and IEC 80601

Forest tested our unit against the same standards as Pelton & Crane Spirit Operative unit. We added IEC 80601-2-60 and tested our conformance to this standard. All tests passed. Although this standard defines the particular requirements for the basic safety and essential performance of dental equipment, compliance with basic safety IEC 60601-1, this particular standard, and essential performance as defined in Forest Dental memo on defining essential performance, assures that we meet our ESSENTIAL PERFORMANCE and safety standards during the intended use of the unit.

5.6.2 Clinical Performance Data:

Electrical, mechanical and general safety performance testing is according to standards of ANSI/AAMI ES60601-1 and the particular standard for dental equipment IEC 80601-2-60. Essential Performance, as defined by the standards and Forest Dental, were tested against pass/fail criteria. This evaluation under the 3rd Edition of the aforementioned general standard also demonstrated compliance with ISO 14971 for risk assessment and IEC 62366 for usability engineering. This system was also evaluated to the EMC standard, IEC 60601-1-2, ISO 7494-1 and ISO 7494-2 (including meeting all ISO requirements contained within 7494-1 and 7494-2). The reports from these evaluations demonstrate compliance to the requirements for medical devices. All tests passed assuring compliance to industry standards for dental equipment and assuring that the technological characteristic differences between the Forest Dental Operative Unit and the predicate device, the Pelton & Crane Spirit Dental

Operative Units (K143696), do not represent any new concerns about substantial equivalence.

From the Clinical Evaluation Report – Dental Units, document # 98-0033a, on file at Forest Dental facility, we conclude the following:

- The overall technology used in the Forest Dental Operative Unit, is not novel, the intended use is common, and the Predicate Delivery Systems have been in use for a considerable length of time.
- The Forest Dental Operative Unit, configured as tested, does not introduce new risks to the user. The product risks are reasonably well-understood.
- The Dental Unit meets the Forest defined Essential Performance requirements as tested.
- The Dental Unit meetings the Essential Requirements in Annex I of the Medical Devices Directive 93/42/EEC.

5.6.3 Non-Clinical Performance Data:

Test reports are available for the following:

Biocompatibility evaluation was conducted in accordance with the FDA Guidance Document and ISO 10993-1 as recognized by the FDA. Cytotoxicity testing according to ISO 10993-5 was conducted on water and air line components and they were found to be non-cytotoxic. Dermal irritation testing has been completed by the manufacturer of the chair upholstery and the upholstery was found to be a non-irritant. Heavy metal analysis was also conducted to show that water line quality is compliant with EPA standards for drinking water.

Sterilization reports in accordance with ISO 17655-1:2006 for the air/water syringe tip, HVE and SE conclude that these reusable components can be sterilized to reach an acceptable sterility assurance level.

Cleaning and disinfection validation was conducted on clinical contact surfaces in accordance with the FDA Guidance Document on Reprocessing Medical Devices.

The Forest dental unit waterlines were validated according to ISO 16954:2015 to conclude that following the reprocessing directions in the instructions for use result in the waterlines being disinfected.

5.6.4 Conclusion as to Substantial Equivalence:

Based on the comparison of intended use, technological characteristics, and performance data, the Forest Dental Operative Unit is substantially equivalent to

the predicate device, Pelton & Crane Spirit Dental Operative Unit. Forest Dental Products, Inc. concludes that the Forest Dental Units are substantially equivalent to the predicate device.