March 11, 2024

SATELEC-ACTEON GROUP
Noelle Zuccarello
Quality Manager
124 Gaither Drive Suite # 140
Mt. Laurel, New Jersey 08054

Re: K233922
Trade/Device Name: SP NEWTRON CAN-A; MODULE NEWTRON CAN-A EMB; SUPPORT XINETIC; NWT CAN SLIM LED CORD G3 SHORT; NWT CAN SLIM LED CORD G3 LONG
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC
Dated: December 5, 2023
Received: December 13, 2023

Dear Noelle Zuccarello:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., RAC, CQIA
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233922

Device Name

- SP NEWTRON CAN-A
- MODULE NEWTRON CAN-A EMB
- SUPPORT XINETIC
- NWT CAN SLIM LED CORD G3 SHORT
- NWT CAN SLIM LED CORD G3 LONG

Indications for Use *(Describe)*

Scaling:
- Interdental junction treatment
- Tooth neck and subgingival treatment
- Treatment of large deposits
- Treatment of coating and tobacco stains
- Interproximal treatment
- Prosthesis conservative/restorative:
  - o Inlay/onlay condensation
  - o Amalgam plugging
  - o Loosening prostheses (bridge, crown, post, pivot...)

Endodontics:
- Canal preparation
- Canal cleaning
- Canal filling
- Gutta percha condensation
- Treatment resumption
- Retro surgery
- Micro retro surgery
- Surface smoothing after burring

Periodontics:
- Root planning
- Initial therapy
- Treatment of periodontal pockets
- Treatment of furcations
- Maintenance therapy

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 – K233922
[As Required by 21 CFR 807.92.c]

I – SUBMITTER

Device Submitter:

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Date Prepared: March 11, 2024

II – DEVICE

Name of Device:

SP NEWTRON CAN-A
MODULE NEWTRON CAN-A EMB
SUPPORT XINETIC
NWT CAN SLIM LED CORD G3 SHORT
NWT CAN SLIM LED CORD G3 LONG

Common or Usual Name: Ultrasonic Scaler

Classification Name: Ultrasonic Scaler (21 CFR 872.4850)

Regulatory Class: II

Product Code: ELC

III – PREDICATE DEVICE

Name of Device	Manufacturer	Product Code	510(k) number	Date Cleared
SP NEWTRON Module	SATELEC	ELC	K033764	March 01, 2004

SP NEWTRON Module Predicate Device has not been subject to a design-related recall.

No reference devices were used in this submission.

IV – DEVICE DESCRIPTION

Key Device components included in this Submission:

- NEWTRON CAN A Module (reference: X55650 and F55660)
- Mounting Bracket (reference: E55072)
- Handpiece Tubing 3 75” (refence: F01212)
- Handpiece Tubing 3 89” (refence: F01213)

Device Characteristics:

The NEWTRON CAN A Module is an Ultrasonic Control Module intended to be integrated in a Dental Delivery System. The NEWTRON CAN A Module contains an Embedded Software.

Environment of Use:

The NEWTRON CAN A Module is intended to be used in Dental Offices (installed in a Dental Delivery System).

Description of the Device:

The NEWTRON CAN A Module is an Ultrasonic Control Module intended to be integrated in a Dental Delivery System manufactured by the American Company named A-DEC. The A-DEC Dental Delivery System provides different functioning information to the NEWTRON CAN A Module such as Ultrasonic Power Setting, Light Command through a communication frame. The communication frame is designed and imposed by A-DEC, the Manufacturer of the Dental Delivery System. The values of Ultrasonic Power Setting and the Light Command are coded and communicated in the communication frame. Ultrasonic Power Setting and the Light Command are driven by the user with a touch pad embedded in the A-DEC Dental Delivery System.

The only parameters of the NEWTRON CAN A Module that can be modified by the A-DEC Dental Delivery System are the values of Ultrasonic Power Setting and the Light Command. The NEWTRON CAN A Module converts a low voltage Power Supply provided by the A-DEC Dental Delivery System into an Ultrasonic Electric Signal.

The NEWTRON CAN A Module is intended to be used in combination with a SATELEC Dental Ultrasonic Handpiece and a SATELEC range of Dental Tips. The electrical signal emitted by the NEWTRON CAN A Module supplies the Dental Ultrasonic Handpiece equipped with SATELEC Dental Tip. The amplitude of the ultrasonic micro-vibrations depends on the electrical Signal provided by the NEWTRON CAN A Module (amplitude). The SATELEC Dental Ultrasonic Handpiece is connected to the Dental Delivery System via a Handpiece cord. Mechanical micro- vibrations are transmitted to a Dental tip attached to the end of the SATELEC Dental Ultrasonic Handpiece.

The NEWTRON CAN A Module is intended to be used in combination with SATELEC Ultrasonic Handpieces previously cleared [NEWTRON Handpiece (K050895 – Apr 20, 2005, K113430 – Feb 23, 2012, K131997 and Nov 26, 2013), NEWTRON SLIM Handpiece (K131997 – Nov 26, 2013 and K132267 – Mar 10, 2014), NEWTRON SLIM B.LED Handpiece (K132267 – Mar 10, 2014 and K132322 – Mar 11, 2014), NEWTRON LED Handpiece (K071424 – Aug 24, 2007, K091331 – Dec 11, 2009 and K091252 – Jul 22, 2009)].

Scientific Principles:

The NEWTRON CAN A Module uses a control system of amplitude or “feedback system”, according to the resistance encountered by the dental tip and the setting mode selected. Likewise, its “frequency tuning capability” finds and constantly adapts the oscillating frequency to supply to the dental ultrasonic handpiece.

Principles of Operation:

The NEWTRON CAN A Module emits an electrical signal to the Dental Ultrasonic Handpiece and adapts it permanently in accordance to the effort and the encountered impedance of the Dental Ultrasonic Handpiece and the user settings. The Dental Ultrasonic Handpiece comprises a piezoelectric ceramic transducer, which converts the electrical signal into ultrasonic micro- vibrations. The amplitude of the ultrasonic micro-vibrations depends on parameters of the electrical Signal provided by the NEWTRON CAN A Module (amplitude, frequency). Mechanical micro- vibrations are transmitted to a Tip attached on the distal part of the ultrasonic Handpiece. The working part of the Tip moves on the clinical site.

Material of Use:

The casing of the NEWTRON CAN A Module is made of thermoplastic materials protected against the fire propagation (self-extinguishing). The thermoplastic materials are certified by the Underwriters Laboratories according to the UL94 standard. The thermoplastic materials are classified UL94V-0. Additionally, the Printed Circuit Boards (PCB) are classified UL 94V-0. Duration and type of contact are not applicable for NEWTRON CAN A Module.

The Handpiece Tubing Cod is made of Silicone and the Irrigation Tubing contained in the Handpiece Tubing is made of Polyurethane. Irrigation Tubing present an indirect contact less than 24 hours.

Key Performance Specifications / Characteristics of the Device:

Output Frequency (KHz) :	28 KHz to 36 KHz
Output Power in the Ultrasonic handpiece:	10 mW to 12 W
Output Current in the Ultrasonic handpiece (mA):	8 ± 10% to 100 +20% -10%

V – INDICATION FOR USE

Scaling:

- Interdental junction treatment
- Tooth neck and subgingival treatment
- Treatment of large deposits
- Treatment of coating and tobacco stains
- Interproximal treatment
- Prosthesis conservative/restorative:
  - Inlay/onlay condensation
  - Amalgam plugging
  - Loosening prostheses (bridge, crown, post, pivot...)

Endodontics:

- Canal preparation
- Canal cleaning
- Canal filling
- Gutta percha condensation
- Treatment resumption
- Retro surgery
- Micro retro surgery
- Surface smoothing after burring

Periodontics:

- Root planning
- Initial therapy
- Treatment of periodontal pockets
- Treatment of furcations
- Maintenance therapy

VI – COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A comparison Between SATELEC NEWTRON CAN A and the Predicate Device is present in Table 01.

Table 01 – Comparison Between SATELEC NEWTRON CAN A and the Predicate Device

	New Device	Predicate Device	Result / Impact of the differences on Safety / Effectiveness
Trade / Device Name	NEWTRON CAN A	SP NEWTRON Module	
Knumber	K233922	K033764	

Intended Use	Scaling:
	• Interdental junction treatment
	• Tooth neck and subgingival treatment
	• Treatment of large deposits
	• Treatment of coating and tobacco stains
	• Interproximal treatment
	• Prosthesis conservative/restorative:
	  • Inlay/onlay condensation
	  • Amalgam plugging
	  • Loosening prostheses (bridge, crown, post, pivot...)
	
	Endodontics:
	• Canal preparation
	• Canal cleaning
	• Canal filling
	• Gutta percha condensation
	• Treatment resumption
	• Retro surgery
	• Micro retro surgery
	• Surface smoothing after burring
	
	Periodontics:
	• Root planning
	• Initial therapy
	• Treatment of periodontal pockets
	• Treatment of furcations
	• Maintenance therapy
		Scaling:
		• Interdental junction treatment
		• Tooth neck and subgingival treatment
		• Treatment of large deposits
		• Treatment of coating and tobacco stains
		• Interproximal treatment
		• Prosthesis conservative/restorative:
		  • Inlay/onlay condensation
		  • Amalgam plugging
		  • Loosening prostheses (bridge, crown, post, pivot...)
		
		Endodontics:
		• Canal preparation
		• Canal cleaning
		• Canal filling
		• Gutta percha condensation
		• Treatmen t resumption
		• Retro surgery
		• Micro retro surgery
		• Surface smoothing after burring
		
		Periodontics:
		• Root planning
		• Initial therapy
		• Treatment of periodontal pockets
		• Treatment of furcations
		• Maintenance therapy
			Identical

	New Device	Predicate Device	Result / Impact of the differences on Safety / Effectiveness
Trade / Device Name	NEWTRON CAN A	SP NEWTRON Module	
Knumber	K233922	K033764	
Product Code	ELC	ELC	Identical
Common or Usual Name	Ultrasonic Scaler	Ultrasonic Scaler	Identical
Classification Name:	Ultrasonic Scaler 21 CFR 872.4850	Ultrasonic Scaler 21 CFR 872.4850	Identical
Regulation Identification	An ultrasonic scaler is a device intended for use during dental cleaning and periodontal (gum) therapy to remove calculus deposits from teeth by application of an ultrasonic vibrating scaler tip to the teeth	An ultrasonic scaler is a device intended for use during dental cleaning and periodontal (gum) therapy to remove calculus deposits from teeth by application of an ultrasonic vibrating scaler tip to the teeth	Identical
Regulatory Class	II	II	Identical
Principle of operation			
Principles of Operation	The Device emits an electrical signal to a Dental Ultrasonic Handpiece and adapts it permanently in accordance to the effort and the encountered impedance of the handpiece and the user settings.		Identical
Dimensions			
Height (mm)	36.6	33	No Impact (#01)
Depth (mm)	59.5	50	No Impact (#02)
Width (mm)	85.95	60	No Impact (#03)
Weight (g)	160	130	No Impact (#04)
Mounting Unit	Embedded in Dental Delivery System	Embedded in Dental Delivery System	Identical
Power Supply			
Typical Voltage (VAC)	24	24	Identical
Minimum Voltage (VAC)	18.8	21.5	No Impact (#05)
Maximum Voltage (VAC	28.5	27.6	No Impact (#06)
Input Frequency (Hz)	50 or 60	50 or 60	Identical
Maximum Current consumption (AC)	1.2	1	No Impact (#07)
Maximum Power Consumption (VA AC)	29	26	No Impact (#08)
Maximum Idle Current Consumption (mA AC)	100	100	Identical
Maximum Idle Power Consumption (VA AC)	2	2	Identical
Pictures			

	New Device	Predicate Device	Result / Impact of the differences on Safety / Effectiveness
Trade / Device Name	NEWTRON CAN A	SP NEWTRON Module	
Knumber	K233922	K033764	
Picture			No Impact (#09)
Electrical Safety Classification			
Electrical Safety Class	B type	B type	Identical
External constitution			
Fire aspects (for Casing)	UL94-V0 (self-extinguishing material)	UL94-V0 (self-extinguishing material)	Identical
Ultrasonic Function Performances			
Electrical Technology	NEWTRON Technology	NEWTRON Technology	Identical
Minimum Output Frequency (KHz)	28	28	Identical
Maximum Output Frequency (KHz)	36	36	Identical
Minimum Output Power in the Ultrasonic handpiece (mW)	10	10	Identical
Maximum Output Power in the Ultrasonic handpiece (W)	12	12	Identical
Minimum Output Current in the Ultrasonic handpiece (mA)	8 ± 10%	8 ± 10%	Identical
Maximum Output Current in the Ultrasonic handpiece (mA)	100 +20% -10%	100 +20% -10%	Identical
Power Factor	More than 0.65	More than 0.65	Identical
Function to power Light in the Ultrasonic Handpiece			
Standard LED Ring Output Current (mA DC)	45	800	No Impact (#10)
Low Voltage LED Ring Output Current (mA DC)	135 ± 15		No Impact (#11)
Maximum Open Voltage (V DC)	14	5	No Impact (#12)
Maximum Short -circuit Current (mA DC)	180	1000	No Impact (#13)
User Interface			
Quantity of Connectors	3	2	No Impact (#14)
Power Supply Connector	1	1 (one the same connector)	No Impact (#15)
Command Connector	1		No Impact (#16)

	New Device	Predicate Device	Result / Impact of the differences on Safety / Effectiveness
Trade / Device Name	NEWTRON CAN A	SP NEWTRON Module	
Knumber	K233922	K033764	
Handpiece Connector	1	1	Identical
Type of Command / Input Setting	Digital Values 0 to 100 Contained in the communication frame	Digital Signal stepped in Volts 0 to 5 Volts	No Impact (#17)
Environmental			
Where used	Dental Office (installed in a Dental Delivery System)	Dental Office (installed in a Dental Delivery System)	Identical
Temperature			
Thermal Cooling	Natural Convection	Natural Convection	Identical
Operating Temperature	+10°C to +30°C	+10°C to +30°C	Identical
Storage Temperature	0°C to +50°C	-20°C to +70°C	No Impact
Humidity			
Operating Humidity	30% to 75%	30% to 75%	Identical
Storage Humidity	10% to 95%	10% to 100%	Identical
Pressure / Altitude			
Operating Pressure	800 hPa to 1060 hPa	800 hPa to 1060 hPa	Identical
Storage Pressure	500 hPa to 1060 hPa	500 hPa to 1060 hPa	Identical
Maximum Operating Altitude	Less than 2000 m	Less than 2000 m	Identical
Safety Standards			
Safety Standard	IEC 60601-1	IEC 60601-1	Identical
EMC Standard	IEC 60601-1-2	IEC 60601-1-2	Identical
Installation Method			
Location of Fixation	Fixed in the Dental Delivery System	Fixed in the Dental Delivery System	Identical
Principles of fixation	Mounting bracket fixed in the Dental Delivery System with 2 screws	Mounting bracket fixed in the Dental Delivery System with 2 screws	Identical

A lot of features and characteristics of NEWTRON CAN A are identical to the Predicate Device. It exists differences between NEWTRON CAN A and the Predicate Device.

Explanation on Differences #01, #02, #03, #04: The SATELEC New Device is embedded in a Dental Delivery System and it is not in contact to the Patient. Differences of Height, Depth, Width and Weight between SATELEC New Device and the Predicate Device has no impact on the Safety and Effectiveness.

Explanation on Differences #05, #06: The Power Supply of the SATELEC New Device is adapted to the Dental Delivery System where it is embedded. The Difference of Minimum and Maximum Voltage (VAC) between SATELEC New Device and the Predicate Device has no impact on the Safety and Effectiveness.

Explanation on Differences #07, #08: The differences of the Current consumption and the Power Consumption (VA AC) are due to Microprocessor of the SATELEC New Device that is permanently activated to drive the SATELEC New Device. Difference of Maximum Current consumption (AC) between SATELEC New Device and the Predicate Device has no impact on the Safety and Effectiveness.

Explanation on Difference #09: Difference of Shape / Presentation between SATELEC New Device and the Predicate Device has no impact on the Safety and Effectiveness.

Explanation on Differences #10, #11: The Predicate Device is intended to power a Bulb whereas the SATELEC New Device powers a LED Ring (Light Diode Emitting). The current value provided by the SATELEC New Device is lower than the Predicate Device due to the characteristic differences between a bulb and LED (LEDs consume a lower current). The Bulb and the LED Ring are parts of the Ultrasonic Handpiece. The Predicate Device powers a Bulb contained in the Ultrasonic Handpiece. The SATELEC New Device powers a LED Ring contained in the NEWTRON SLIM B.LED Handpiece (K132267 – Mar 10, 2014 and K132322 – Mar 11, 2014), NEWTRON LED Handpiece (K071424 – Aug 24, 2007, K091331 – Dec 11, 2009 and K091252 – Jul 22, 2009). Difference of Standard LED Ring Output Current (mA DC) and Low Voltage LED Ring Output Current (mA DC) between SATELEC New Device and the Predicate Device has no impact on the Safety and Effectiveness.

Explanation on Difference #12: The Predicate Device is intended to power a Bulb whereas the SATELEC New Device powers a LED Ring (Light Diode Emitting). The Voltage value provided by the Predicate Device is lower than the SATELEC New Device due to the characteristic differences between a bulb and LED (Bulb needs a low voltage). The Bulb and the LED Ring are parts of the Ultrasonic Handpiece. The Predicate Device powers a Bulb contained in the Ultrasonic Handpiece. The SATELEC New Device powers a LED Ring contained in the NEWTRON SLIM B.LED Handpiece (K132267 – Mar 10, 2014 and K132322 – Mar 11, 2014), NEWTRON LED Handpiece (K071424 – Aug 24, 2007, K091331 – Dec 11, 2009 and K091252 – Jul 22, 2009). Difference of Maximum Open Voltage (V DC) between SATELEC New Device and the Predicate Device has no impact on the Safety and Effectiveness.

Explanation on Difference #13: The Predicate Device is intended to power a Bulb whereas the SATELEC New Device powers a LED Ring (Light Diode Emitting). The current value provided by the SATELEC New Device is lower than the Predicate Device due to the characteristic differences between a bulb and LED (LEDs consume a lower current). Because the SATELEC New Device provides less output current for LED Ring than the Predicate Device, the value of the Maximum Short-circuit Current (mA DC) is reduced.

The Bulb and the LED Ring are parts of the Ultrasonic Handpiece. The Predicate Device powers a Bulb contained in the Ultrasonic Handpiece. The SATELEC New Device powers a LED Ring contained in the NEWTRON SLIM B.LED Handpiece (K132267 – Mar 10, 2014 and K132322 – Mar 11, 2014), NEWTRON LED Handpiece (K071424 – Aug 24, 2007, K091331 – Dec 11, 2009 and K091252 – Jul 22, 2009). Difference of Maximum Short -circuit Current (mA DC) between SATELEC New Device and the Predicate Device has no impact on the Safety and Effectiveness.

Discussion #14: Difference of Quantity of Connectors between SATELEC New Device and the Predicate Device has no impact on the Safety and Effectiveness.

Discussion #15: The Predicate Device includes the Power Supply Connector and the Command connector in the same connector whereas the SATELEC New Device is equipped by two dedicated connectors. Difference of Power Supply Connector between SATELEC New Device and the Predicate Device has no impact on the Safety and Effectiveness.

Discussion #16: The Predicate Device includes the Power Supply Connector and the Command connector in the same connector whereas the SATELEC New Device is equipped by two dedicated connectors. Difference of Command Connector between SATELEC New Device and the Predicate Device has no impact on the Safety and Effectiveness.

Discussion #17: The Type of Command / Input Setting is designed and adapted only for the Dental Delivery System manufactured by A-DEC. The SATELEC New Device receives digital information (Digital Values) provided by the Dental Delivery System. The Command / Setting of the SATELEC New Device translates digital information into analogic setting used by the analogic structure contained in the Device. The method of setting of the SATELEC New Device has slightly changed from the Predicate Device. The A-DEC Dental Delivery System uses a digitally stepped signal to transfer output power setting (input setting comprised between 0 and 5 Volts by steps) to the Predicate Device, the A-DEC

Delivery System send the same output power setting to the SATELEC New Device utilizing CAN bus messages (digital setting 0 to 100 by steps). The Output Current provided to the Ultrasonic Handpiece by the SATELEC New Device are the same as the Predicate Device. Difference of Type of Command / Setting between SATELEC New Device and the Predicate Device has no impact on the Safety and Effectiveness.

The Identified differences are not critical to the intended therapeutic Use and do not affect the Safety and Effectiveness of the SATELEC New Device.

VII – PERFORMANCE DATA

Electromagnetic Compatibility Test: The Electromagnetic Compatibility Tests have been performed according to IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances -- requirements and tests **(**Recognition Number 19-8).

Electrical Safety Tests: The Electrical Safety Tests have been performed according to IEC 60601-1:2005(R) 2012 and A1:2012, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety And Essential Performance **(**Recognition Number 19-4) included USA Deviations.

Software Verification and Validation: The Software Verification and Validation activities were conducted and documented according to the document named "*Content of Premarket Submissions for Device Software Functions – Guidance for Industry and Food and Drug Administration Staff*" dated June 14th, 2023.

Biocompatibility Validation: The Biocompatibility Tests have been performed for Irrigation Tubing contained in the Handpiece Tubings according to applicable Standards for Accessories in contact to the Patient. Tests were conducted according to the ISO 10993-1: 2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (Recognition Number 2-258), more specifically according to the standards: ISO 10993-5: 2009, Biological evaluation of medical devices - Part 23: Tests for irritation (Recognition Number 2-245), ISO 10993- 10: 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization (Recognition Number 2-296), ISO 10993-11: 2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (Recognition Number 2-255), ISO 10993-17 - Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (Recognition Number 2-237), ISO 10993-18 - Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (Recognition Number 2-276), ISO 10993-23: 2021, Biological evaluation of medical devices - Part 23: Tests for irritation (Recognition Number 2-291) and Pyrogenic response according to US Pharmacopeia (General chapter <151>) completed by Pyrogenic response according to European Pharmacopeia (chapter 2.6.8).

Performance Testing bench: The comparison of performances between NEWTRON CAN A and Predicate Device has been performed. The Technical Characteristics for NEWTRON CAN A (Maximum Idle Consumption, Maximum Consumption, Output Currents, Output Frequencies) are similar to the Predicate Device SP NEWTRON Module (K033764, cleared March 01, 2004).

VIII – CONCLUSION

Following all information contained in this Pre-Market Notification Submission File, we can declare that the SATELEC NEWTRON CAN A is Substantially Equivalent (SE) to the SATELEC Predicate Device SP NEWTRON Module (K033764, cleared March 01, 2004).

End of Section

(No other information after this line expect Appendix if applicable)