October 19, 2022

Olsen Indústria e Comércio S.A.
℅ Lilian Llull
Regulatory Affairs Manager
TechLink International
16445 Collins Ave # 522
Sunny Isles, Florida 33160

Re: K213742
Trade/Device Name: Infinity Pro, Logic, Quality, Sprint
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit And Accessories
Regulatory Class: Class I, reserved
Product Code: EIA, EBW
Dated: September 19, 2022
Received: September 19, 2022

Dear Lilian Llull:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213742

Device Name
Infinity Pro, Logic, Quality, Sprint

Indications for Use *(Describe)*
Infinity Pro, Logic, Quality, Sprint are intended for use in general dental applications by providing the dental practitioner a user interface to control operation of the dental chair and attached dental devices. The system delivers air, water, electricity, and vacuum to allow the dental practitioner an intuitive control center for all common and normal patient treatment procedures performed by the dentist / dental assistant.

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
K213742

I. SUBMITTER

Olsen Indústria e Comércio S.A.
Avenida Ivo Lucchi, 68 - Jardim Eldorado
Palhoça, SC. 88133-510, Brasil
Phone: +5548 2106-6000
Fax: +5548 2106-6000

Official Contact:

Lilian Llull
TechLink International Consulting
16445 Collins Ave # 522 Sunny Isles, FL 33160
TEL – (305) 206-6777
Date Prepared: Oct 14, 2022

II. DEVICE

Name of Device: Infinity Pro, Logic, Quality, Sprint
Common or Usual Name: Unit, Operative Dental
Classification Name: Dental Operative Unit and Accessories, per 21CFR 872.6640
Regulatory Class: Class I
Product Code: EIA
Additional Product Code: EBW
Classification Panel: Dental

III. PREDICATE DEVICE

Olsen Infinity / Infinity Cross Flex Dental System, K180935

IV. DEVICE DESCRIPTION

The Olsen dental units consist of a patient chair, foot control, dentist element, assistant element, water unit and a dental operating light. The Olsen dental units also include coupling for various handpieces and accessories that can be added to the Olsen Dental System such as pneumatic handpieces, handpieces with generator, optical fiber handpieces, pneumatic scalers, air/water syringes, SE (saliva ejectors) and handpieces for vacuum.
None of the Olsen dental units, parts or accessories are provided sterile.
Infinity Pro, Logic, Quality and Sprint Dental Systems serves as a base that includes components to deliver air, water, electricity, and vacuum to dental handpieces instruments.

The Infinity Pro, Logic, Quality and Sprint Dental Systems are designed to bring a patient into an ergonomic position to perform dental treatment procedures. For this purpose, the patient chair (seat and backrest) can be brought into an appropriate position, either by activating the chair positioning motors or by recalled programmed positions set by the user.
Upholsteries can be provided on PVC and a built-in massage system is available for backrest and seat. The headrest is adjusted manually according to patient height and the area in the patient's oral cavity to be treated. The headrest has mechanical adjustment that allows adjustments such as extension / retraction to adapt to the patient's stature, tilting for maxillary / mandibular treatment.

To perform the treatment, pneumatic instruments coupled to the equipment such as high speed turbines and low speed micromotors are applied by the intended user. After taking an instrument from its respective holder, it can be activated via the foot control. The air pressure for activating the instruments is pre-set at the factory, but the adjustment of the volume of water for cooling the instruments can be adjusted by the user. The optical fiber coupling, in addition to water and air, provides electricity to activate the internal lighting of this type of instrument. There is available system of continuous air jet for highspeed handpieces couplings.
Water for instruments is self-contained, and an internal water heater is available for patient comfort. The Olsen Dental Systems provide stainless steel trays to place dental hand instruments and materials required during treatment.

To dispose of fluids and particles deriving from the oral cavity during treatment, suction hoses with attached instruments are provided on the assistant element or Water Unit. After taking the ejection instrument from its respective holder, continuous ejection starts until instrument come back to its holder. There is also available handpiece ejector activated by command button located on chair base or foot control. Vacuum pump adaptor is also available to provide one or two handpieces connected to a vacuum line.

Also, a cuspidor bowl is available for patient rinse. The cuspidor is swivel at 90° and can be manually approached to the patient chair. Cup Filler is available for patient mouth rinse. The Spittoon Bowl can be supplied in polyester resin or porcelain. Water to Spittoon Bowl and Cup Filler is city water. Manual or automatic commands for water to spittoon bowl and cup filler are available.

An operating light providing illumination to the oral cavity can be switched ON via the touch panel, pedal, chair base commands or is operated automatically in accordance with preset adjustments in connection with the pre-programmed chair positions. It can be also switched ON/OFF via a no-touch sensor that recognizes when the hand is moved there.

Most chair and instrument related functions can be activated hands-free via foot control. The foot control is provided as progressive pedal for handpieces activation and other commands on the chair base for Quality and Sprint units, or all activation and commands combined in a remote foot pedal, available to Quality and Sprint as optional item and to Logic and Infinity Pro as standard item.

Accessories:

- Cart System
- Dental Cart Unit K10
- Monitor Holder
- Junction Box

The Cart System and Dental Cart Unit K10 are optional items that eliminates the use of a support arm connected to the Delivery Unit and provides the dentist element (working table) instrument couplings, 3-Way Syringe and features on a steel base with castors, which provides mobility for the professional.
Dental Cart Unit K10 holds up to 10 handpieces including ejection and vacuum handpieces, concentrating all handpieces in one place.
Connection to the chair by a single hose for water, air, and 24V electricity supply.

The Monitor Holder is an optional item that is attached to the operating light column with a fixing ring to support one monitor. The monitor holder features swivel on the shaft, tilt adjustment and side swivel for the monitor.

The Junction Box works as a passage and connection of water, sewage, and electricity network, for connecting the equipment and the optional Cart System or Dental Cart Unit K10 or when the customer requests a connection point other than the junction box integrated in the base of the equipment.

The device description and intended use are identical for all Olsen Dental Unit models. The differences between the models and mounting configurations are cosmetic in nature such as size/shape of the operative units (working tables) and instrument holders. All critical components within the Olsen Dental Systems are the same.

V. INDICATIONS FOR USE

Infinity Pro, Logic, Quality, Sprint are intended for use in general dental applications by providing the dental practitioner a user interface to control operation of the dental chair and attached dental devices. The system delivers air, water, electricity, and vacuum to allow the dental practitioner an intuitive control center for all common and normal patient treatment procedures performed by the dentist / dental assistant.

The Indications for Use statement for the Olsen Infinity / Infinity Cross Flex Dental System device is not identical to the predicate device due the “electricity” term; however, the difference does not alter the intended therapeutic use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for dental procedures performing, by patient accommodation and provision of lighting, and conditions for operating dental instruments.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Subject Device and Predicate Device Comparison Table:

		Infinity Pro, Logic, Quality, Sprint (Subject Device)	**Infinity and Infinity Cross Flex (Predicate Device)**
Construction		CHAIR / DELIVERY UNIT / WORKING TABLE / ASSISTANT MODULE / OPERATING LIGHT / FOOT PEDAL / STOOL	CHAIR / DELIVERY UNIT / WORKING TABLE / ASSISTANT MODULE / OPERATING LIGHT / FOOT PEDAL / STOOL
Chair	Headrest	Single and Double-Articulating Headrest	Double-articulating headrest
	Safety switch function	Emergency Stop Switch and/or a Stop System	Emergency Stop Switch and a Stop System,
	Stop function	The safety switch and/or any movement switch stops the chair operation	The safety switch stops the chair operation.
	Programmable chair position	Programmable chair position: Total 3 positions	Programmable chair position: Total 3 positions
	Operation	The chair performs seat and backrest movements individually and independently through spindle drive motors.	The chair performs seat and backrest movements individually and independently through spindle drive motors.
	Chair Operating System	Electric System	Electric System
	Chair Controls	Available on chair base, remote pedal, or touch panel.	Available on remote pedal and touch panel.
	Construction and Material	Metal Frame built with SAE 1020. Upholstery coated with PVC, built with injected foam.	Metal Frame built with SAE 1020. Upholstery coated with PVC, built with injected foam.
	Optional Item	Anti-Stress System	Not available
UNIT/CHAIR form type		Over-arm Contour type	Over-arm Contour type
Delivery Unit Working Table	Working Table Arm	Mechanical or pneumatic brake Free Horizontal Moments	Pneumatic brake Free Horizontal Moments
	Handpiece holder	3 or 4 steady holders (up to 5 or 6 optional)	4 steady holders (up to 6 optional)
		Retractable Rods Available (optional)	Retractable Rods available (Cross Flex)
	Handle	Adjustable handle	Adjustable handle
	Touchpad	Capacitive Panel	Capacitive Panel
	Handpiece water and air cooling	Only water is adjustable	Only water is adjustable
	Flex arm tension	Not available	Not available

	Working Table Relative position to the chair	Both Sides (Ambidextrous)	Left Side (Standard)
	Stainless Steel Tray	Available	Available
	Optional Items	Coupling for Optical Fiber Handpieces, X-Ray Viewer, Air Jet, Thermo Comfort, Chronolub.	Not available
Water Unit	Cuspidor (Spittoon)	Spittoon bowl / Rinsing pipe	Spittoon bowl / Rinsing pipe
	Water System	City Water / Distilled Water	City Water / Distilled Water
	Valves Composition (fluid contact area)	Stainless Steel 316L	Stainless Steel 316L
Support Center	Cuspidor	Attach/detachable POLYESTER or PORCELAIN, disassemble for cleaning	Attach/detachable POLYESTER, disassemble for cleaning
	Solids collector	Equipped	Equipped
	Distilled water reservoir	Equipped	Equipped
	Cup water system	Available	Not available
Vacuum system		Central Vacuum system or Air Vacuum System	Central Vacuum system or Air Vacuum system
3-Way Syringe		Adjusting the Water / Air / Spray function is used in the syringe button	Adjusting the Water / Air / Spray function is used in the syringe button
Accessories Tools	Accessories holder	SE, Vortex Ejector, 3-WAY syringe and Vacuum Pump Adaptor attached	SE, 3-WAY syringe and Vacuum Pump Adaptor attached
	Holder structure	Rotation and individual holder	Rotation and individual holder
Operating Light	Light head structure	3-axis and 2-axis head adjustment method	3-axis head adjustment method
	Description	ABS made, with multifaceted mirror, with gradual and cyclical intensity control	ABS made, with multifaceted mirror, with gradual intensity control
	Technical Features	LED: 3,7V x 3VA / LED 12-24V x 12VA Luminosity: 8.000 to 30.000 Lux Color Temperature: 4500K	LED: 24V x 5W. Luminosity: 4.000 to 24.000 Lux Color Temperature: 4500K
	ON/OFF control	Auto and manual ON/OFF	Auto and manual ON/OFF
Accessories	Accessories attached to the device	Dental Chair / 3-way syringe	Dental Chair / 3-way syringe
	Other	Cart System, Dental Cart Unit K10, Monitor Holder, Junction Box	Dental Cart Unit K10
Operation Method		Control panel / Assistant control panel / Foot controller / Chair Base Commands	Control panel / Assistant control panel / Foot controller
Electric Information	Power Supply / Frequency	AC 118V/127V/220V/230V 50/60Hz	AC 118V/127V/220V/230V 50/60Hz

	Power Shock Protection	Class I	Class I
	Electric Protection	B Type	B Type
Dimesions (mm)		Infinity Pro: 2232 x 2176 x 3216 Logic: 2273 x 2043 x 3355 Quality: 2308 x 1975 x 2623 Sprint: 2268 x 1971 x 2650	Infinity: 2258 x 2176 x 3215 Infinity Cross Flex: 2258 x 2176 x 3374

The following items are considered as common technological principles for both subject and predicate device:

- Dental Chair with backrest and seat with movements through electric motors, to accommodate patient in an ergonomic way to perform dental procedures.
- Adjustable headrest for positioning and access to the patient's oral cavity.
- Base that includes components to deliver air and water to in appropriate conditions for the correct performance of dental handpieces.
- Provide Ejection and Vacuum options to dispose fluids and particles deriving from oral cavity during treatment, where ejection works with venturi system using compressed air that feeds the equipment and vacuum is generated by an external vacuum pump.
- Provide cuspidor bowl for patient rinse supplied with city water.
- Operating Light with multifaceted mirror reflector generates LED illumination and it has a range of motion that allows positioning for the necessary lighting to carry out the dental procedure.
- Foot control for handpieces activation and chair movements commands in order to provide a hands-free equipment operation.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Dental Chair, with adjustable headrest to receive and position the patient.
- Borden or Midwest coupling provides compressed air for propulsion and cooling water for rotary dental instruments.
- 3-Way Syringe to emits air and water jet or spray (mixture of both).
- Venturi Saliva Ejector for patient oral cavity ejection.
- Vacuum Pump Adaptor for patient oral cavity ejection.
- Concept Plus and LED Premium operating lights with 3 adjustment axes, multifaceted mirror for indirect LED Illumination and jointed arm support.
- Remote foot control for hands-free operation of handpieces and chair movements.

The following technological differences exist between the subject and predicate devices:

- Midwest coupling with 3,1V electrical feeding for optical fiber handpieces.
- Continuous air jet through the highspeed coupling itself, dispensing the use of a syringe for this function.
- Thermo Comfort System which is a water heater to provide warm water in the 3-way syringe with the output between 35°C and 45°C.
- Chair Base Commands: Sprint and Quality Dental Units present as serial item the command switches located on the chair base. The positioning of the commands on the base does not

interfere with the performance of the dental procedure or with the safety of using the equipment. Remote foot pedal as an optional item.

- Stop System instead of Emergency Stop Switch: the equipment is not supplied with the Emergency Stop Switch but instead includes a Stop System located close to the operator (user). As for the electrical issue, the ON/OFF switch is located in the same place where Emergency Stop Switch should be, to cut off the device's main power supply if necessary.
- Stop function: All chair movement command buttons can stop the chair operation and not only one safety switch, does not matter if it is located on the remote foot pedal, equipment chair base or equipment panel commands.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Olsen Dental Unit was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. Testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Parts considered tissue contact, direct:
Chair Upholstery – PVC
3-Way Syringe including Tip (internal duct) – Stainless Steel 316L

Parts considered indirect contact:
Internal fluids distribution system: Reservoir, Valves, hoses, couplings – PET Polyester, Stainless Steel 316L, Polyamide (Nylon 6.6) and Ether Based Polyurethane

All parts come into contact with the patient for a period of less than 24 hours.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Olsen Dental Units, consisting of the Chair, Delivery Unit, Water Unit, Working Table with support arm, Operating Light with support arm, Foot Controls and Assistant Module. The equipment complies with the following standards for safety and EMC: IEC 60601-1, ISO 7494-1, ISO 7494-2, IEC 60601-1-2 and IEC 80601-2-60.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern because the functions related to the essential performance are Class moderate and derived from structures mostly LEVEL OF CONCERN MODERATE. Comparative performance testing of the functions of the integrated accessories as compared to the cleared stand-a-lone device. For the foot pedal, software verification/validation of the functions of the foot control was conducted.

Reprocessing Validation

The 3-way syringe is supplied non-sterile and is to be sterilized by autoclave prior to use.

Fractional pre-vacuum cycle at 132°C for 4 min and a drying time of 25.

The sterilization cycle has been validated as below:

- ANSI AAMI ST7, Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ISO 17665-1 and -2, Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices

The cleaning method has been validated per AAMI TIR30 and the FDA Guidance Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.

The intermediate-level disinfection method has been validation for the surfaces and internal hoses/waterlines per AAMI TIR12.

Animal Study
No Animal Studies were conducted.

Clinical Studies
No Clinical Studies were conducted.

VIII. CONCLUSIONS

Subject device has the same method of development, design and assembly, same composition, technical specifications, technological and operational principles, same intended use, and has the same performance and safety tests. The non-clinical data support the safety of the device and the hardware and software verification, and validation demonstrate that the Olsen Dental System, Infinity Pro, Logic, Quality, Sprint should perform as intended in the specified use conditions and performs comparably to the predicate device that is currently marketed for the same intended use.

The different technological characteristics do not raise new concerns of substantial equivalence. The performance data and testing of the Olsen Dental System, Infinity Pro, Logic, Quality, Sprint are the same. Hence, the device is deemed to be substantially equivalent.