February 7, 2025

BDC Dental Corporation Ltd.
℅ Dave Kim
FDA Regulatory Consultant
Mtech Group LLC
7505 Fannin St. Suite 610
Houston, Texas 77054

Re: K242404
Trade/Device Name: BDC Dental Unit
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: Class I, reserved
Product Code: EIA, KLC
Dated: January 10, 2025
Received: January 10, 2025

Dear Dave Kim:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

MICHAEL E. ADJODHA -S

Michael Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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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)*

K242404

Device Name

BDC Dental Unit

Indications for Use *(Describe)*

The BDC Dental Unit is intended to supply power to and serve as a base for dental devices and accessories. This device includes a dental chair and is intended for use in the dental clinic environment and is designed for use by trained dental professionals, dentists and/or dental assistants.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

K242404

I. SUBMITTER

Date:	February 4, 2025
Submitter's Name:	BDC Dental Corporation Ltd.
Submitter's HQ Address:	Part 3, No. 1 Guanchong Section, Shilian Rd., Shiqi Town, Panyu District, Guangzhou, 511450 Guangdong, P.R.China
Submitter's Telephone:	020-32052929
Contact Person:	Yanfei Liu, mr@o-bdc.com, RA Manager

II. PROPOSED DEVICE

Trade/proprietary Name:	BDC Dental Unit
Model Name: :	N1, N2, N3, N1 Plus, N2 Plus, N3 Plus, S1, S2, S3, S1 Plus, S2 Plus, S3 Plus
Regulation Name:	Dental Operative Unit and Accessories
Regulation Number:	21 CFR 872.6640
Product Code:	EIA, KLC
Regulatory Class:	Class I, reserved

III. PREDICATE DEVICE

510(k) Number:	K213932
Primary Manufacturer:	A-dec Inc.
Device Name:	A-dec 500
Regulation Name:	Dental Operative Unit and Accessories
Regulation Number:	21 CFR 872.6640
Product Code:	EIA
Regulatory Class:	Class I, reserved

IV. DEVICE DESCRIPTION

The BDC dental unit is intended to supply air, water, vacuum and electrical power to allow the dental practitioner an intuitive control center for all common and normal patient treatment procedures performed in the dental operatory.

The BDC dental unit consists of a patient chair, dentist element (tray table), assistant element (3-way syringe, high volume evacuator and saliva ejector), side cabinet support center, foot control, cuspidor and a dental operating light, which for patient to sit during the dental diagnosis, treatment and/or operation.

Components: The BDC dental unit consists of a patient chair, dentist element (tray table), assistant element (3-way syringe, high volume evacuator and saliva ejector), side cabinet support center, foot control, cuspidor and a dental operating light, which for patient to sit during the dental diagnosis, treatment and/or operation, these components are devices such as dental handpieces can be connected to the dental unit. Dental handpieces are not included in the BDC Dental Unit. The components of the BDC Dental unit are intended to be covered with an FDA cleared disposable barrier and reprocessed (e.g., cleaning, disinfection, and/or sterilization) per the instructions for use.

Brief of differences between all models

Model	Dentist Element (Traditional)	Dentist Element (Traditional Cart Type)	Dentist Element (Continental)	Dentist Element (Continental Cart Type)	Left/right Arm Swivel	Disc foot control	Lever foot control
N1	√					√	
N2		√				√	
N3	√						√
N1 Plus			√			√	
N2 Plus				√		√	
N3 Plus			√				√
S1	√				√	√	
S2		√			√	√	
S3	√				√		√
S1 Plus			√		√	√	
S2 Plus				√	√	√	
S3 Plus			√		√		√

V. INDICATIONS FOR USE

The BDC Dental Unit is intended to supply power to and serve as a base for dental devices and accessories. This device includes a dental chair and is intended for use in the dental clinic environment and is designed for use by trained dental professionals, dentists and/or dental assistants.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 2

Items	Subject device	Predicate device	Comparison
Manufacturer	BDC Dental Corporation Ltd.	A-dec Inc.	——
510(k) Number	K242404	K213932	——
Product name	Dental Unit	A-dec 500 Delivery System	
Model	N1, N2, N3, N1 Plus, N2 Plus, N3 Plus, S1, S2, S3, S1 Plus, S2 Plus, S3 Plus	A-dec 500	——
Design	The BDC dental unit is mainly composed of a patient chair, dentist element(tray table, 3-way syringe), assistant element (3-way syringe, high volume evacuator and saliva ejector), side cabinet support center, foot control, cuspidor and a dental operating light.	A-dec 500 dental system is composed of dental chair, delivery system, assistant arm, dental light, cuspidor.	Similar
Indications for Use	The BDC Dental Unit is intended to supply power to and serve as a base for dental devices and accessories. This device includes a dental chair and is intended for use in the dental clinic environment and is designed for use by trained dental professionals, dentists and/or dental assistants.	The A-dec Delivery System is intended to provide a mounting location in addition to providing air, water, vacuum, and electrical power to dental devices for use during diagnostic and therapeutic treatment by licensed health care professionals. Delivery systems may be mounted to dental chairs, dental carts, dental cabinets, and walls.	Similar

Dentist Element	- Control of water and air supply, Table Height, Patient Chair Positioning, Light On/Off, Handpiece Function, Timer, Mode Selection	-Turn on/Turn off the air, water, and power, Position the Delivery System, Position the Handpiece Holders, Operate Touchpad Lockout, User Setting and Auxiliary Device Control, Position the Chair, Operate the Dental Light, Operate the Cuspidor, Operate Handpiece	Same
Assist Table (Assistant Element)	- Components: 3-way Syringe, Saliva Ejector, High Volume Evacuator (Large Saliva Ejector) - Control of Light On/Off, Cup/ Spittoon (Cuspidor) Water Dispenser, Changing the Settings, Position memories	-Components: Syringe, Saliva Ejector, High Volume Evacuator -Position the Handpiece Holders, Adjust the Worksurface and Instrumentation Height, Operate the Dental Light, Operate the Cuspidor	Same
Main Components	The BDC dental unit is mainly composed of a patient chair, dentist element(tray table, 3-way syringe), assistant element (3-way syringe, high volume evacuator and saliva ejector), side cabinet support center, foot control, cuspidor and a dental operating light.	Dental system is composed of dental Chair , delivery system, assistant arm, dental light , cuspidor.	Same
Control of water and air	Uses pneumatically controlled vales to water control the flow of air and water on /off and intensity controlled by foot control.	Use air coolant and water coolant to adjust Air and water, speed controlled by foot control.	Same
Software-controlled components	Software functions are reflected in the dentist element and assistant element panel .Software can control dental patient chair up, down, tilt forward, tilt backward and set treatment position, dental operating light on/off, cuspidor flush and cup-filler.	Software functions are reflected in the delivery system and assistant arm panel . Software can control dental chair base up, down, and set treatment position, dental light on/off/ intensity, bowl flush and cupfill, handpieces, electric handpiece.	Similar
Table (Dentist Element)	- Control of water supply, scaler vibration power, table height, patient position, System Power, Film viewer, Patient Chair Positioning, Light On/Off, Handpiece function, Timer, Mode Selection, LED Display	- Control of water and air supply, Table Height, Patient Chair Positioning, Light On/Off, Handpiece Function, Timer, Mode Selection	Similar
Assist Table (Assistant Element)	- Accessories: Saliva Ejector (Small, Large), 3-way Syringe - Control of Light On/Off, Cup/Spittoon Water Dispenser, Changing the Settings, Position memories	- Components: 3-way Syringe, Saliva Ejector, High Volume Evacuator (Large Saliva Ejector) - Control of Light On/Off, Cup/ Spittoon (Cuspidor) Water Dispenser, Changing the Settings, Position memories	Same

Main Components	Chair, Unit, Table, Seat, Stool, Monitor Arm, Operation table	Chair, Unit (side cabinet support center), Table (Assistant Element), Seat (Upholstery Seat), Stool, Operation table (Dentist Element)	Same
Power& Utility Supply	AC110- 120 / 220-240V, 50/60Hz, compressed air and water	AC100- 120/220-240V, 50/60Hz, compressed air and water	Same
Syringe	3-way syringe	3- way syringe	Same
Control of water and air	Uses pneumatically controlled vales to water control the flow of air and water on/off and intensity controlled by foot pedal	Uses pneumatically controlled vales to water control the flow of air and water on /off and intensity controlled by foot pedal.	Same
Air Pressure	0.55-0.8MPa / 5.5-8.0bar	550kPa(min)/800kPa(max)	Similar
Water Pressure	0.20-0.40MPa / 2.0-4.0bar	410±140 kPa	Similar
Dental unit handpiece hose	Air flow rate:300Kpa,max.68NL/min Spray air flowrate:250Kpa,max.18NL/min Water flow rate:250Kpa,max.75mL/min	N/A	
Water System	City water supply	City water supply	Same
Water Heater	Max. (< 42 ◦ C)	Max. (< 42 ◦ C)	Same
Water Sanitation System	Distilled water container added	Distilled water container added	Same
Suction	HVE (High Volume Evacuator) Saliva Ejector	HVE (High Volume Evacuator) Saliva Ejector	Same
Patient Load	Max. 150kg	Max. 227kg	Similar
Chair Height	Max.780±10mm, Min.380±20mm	Max.780±10mm, Min.460±20mm	Similar
Backrest range	110°-180°	N/A	
Head rest range	0-100mm	N/A	
Lift Motor	Hydraulic electromotor	Electromotor	Similar
Dental light	Available	Available	Same
Foot control	Standard	Disc Type	Similar
Electrical Safety	Complied with IEC 60601- 1	Complied with IEC 60601- 1	Same
Electromagnetic compatibility	Complied with IEC 60601- 1-2	Complied with IEC 60601- 1-2	Same

Substantial Equivalence Discussion

The proposed BDC and predicate device are similar in all the items in the comparison chart except water pressure, patient load, chair height, back/head rest, lift motor, foot control and models. These differences do not affect substantial equivalence, also the subject device safety was verified with testing according to IEC 80601-2-60 and IEC 60601- 1.

As the models/types do not differ significantly in purpose, design, materials, energy source, function or any other feature related to substantial equivalence.

On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate device.

VII. Non-Clinical Test Data

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

Biocompatibility testing

The biocompatibility evaluation for the 3-way syringe , high-volume suction, saliva ejector, and tubing were conducted with the following performance standards:

ISO 10993-5: 2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993- 10: 2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization

The 3-way syringe, high-volume suction, saliva ejector, and tubing of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The tubing and syringes body are considered as indirect tissue contacting.

Such like armrest pad, dental operating light handles, upholstery seat, 3-way syringe, high volume evacuator and saliva ejector, we recommended using a barrier sleeves and barrier film which is non-sterile and intended for single patient use only.

Reprocessing Validation

Reprocessing validation was conducted per FDA Guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Guidance for Industry and Food and Drug Administration Staff (fda.gov)" including cleaning, disinfection, and sterilization validation for the components of the BDC Dental Unit.

As to the body/head of the 3-way syringe, high-volume evacuator, and saliva ejector, even though we conducted the Cleaning, intermediate disinfection testing on them, due to their connection which is fixed, the user can not disassembly them from the tubing, so we recommended in our IFU not only the cleaning and disinfection method, but also we recommend to wear compatible FDA-cleared disposable barriers when using them. Cleaning and Sterilization validation was conducted for the 3-way syringe tip.

In addition, cleaning and disinfection validation was provided for the surfaces of the subject device. Cleaning and disinfection validation was conducted on the waterlines and water bottles of the subject device. Validation was conducted using the standard 16954:2015 Dentistry – Test methods for dental unit waterline biofilm treatment.

Electrical safety and electromagnetic compatibility (EMC)

The Electrical Safety and Electromagnetic compatibility tests were performed in accordance with the following standards. Comprehensive performance testing has been conducted on the BDC dental unit in accordance FDA recognized standards. EMC testing was conducted in accordance with Standard EN/IEC 60601- 1-2. Electrical, mechanical, and environmental safety testing according to Standard EN/IEC 60601- 1was performed and IEC 80601-2-60 Particular requirements for the basic safety and essential performance of dental equipment.

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, "Content of Premarket Submissions for Device Software Functions." The software for this device was considered as a "BASIC" level of concern, since a failure or latent flaw in the software would not directly result in serious injury or death to the patient or operator.

Performance Test

The performance tests were conducted as bench test and the test results met the pre-set criteria.

- ISO 7494-1 Third edition 2018-06 - Dentistry - Dental units - Part 1: General requirements and test methods
- ISO 7494-2 Second edition 2015-01 - Dentistry - Dental units - Part 2: Water and air supply
- ISO 9168 - 2009-07-15 - Dentistry - Hose connectors for air driven dental handpieces devices

Clinical Testing

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.

VIII. CONCLUSIONS

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, the BDC dental unit is substantially equivalent to K3, the predicate device, in intended Use/indications for use, material composition, fundamental engineering technology, the principle of operation and basic design.