March 21, 2025

DENTIS Co., Ltd.
% Soojung Moon
CEO
Allura Medical Solution, Inc.
5485 Rathdrum Way
Antioch, California 94531

Re: K241065
Trade/Device Name: ChecQ (AC100)
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EKX
Dated: December 13, 2024
Received: February 27, 2024

Dear Soojung Moon:

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,

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)*

K241065

Device Name

ChecQ (AC100)

Indications for Use *(Describe)*

ChecQ is indicated for use in measuring the stability of implants in the oral cavity and maxillofacial region.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K241065 - 510(k) Summary March 20, 2025

510(k)#: K241065		
Contact Detail		
Applicant Name	DENTIS Co., Ltd.	
Applicant Address	99, Seongseoseo-ro, Dalseo-gu Daegu 42718 Korea, South	
Applicant Contact Telephone	+82535893499	
Applicant Contact	Mr. Gyeong-Seob Kim	
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Correspondent Name	Allura Medical Solution, Inc.	
Correspondent Address	5485 Rathdrum Way Antioch CA 94531 United States	
Correspondent Contact Telephone	+1(407)242796	
Correspondent Contact	Mr. SOOJUNG MOON	
Correspondent Contact Email	sjmoon@alluramеds.com	
Device Name		
Device Trade Name	ChecQ (AC100)	
Common Name	Dental handpiece and accessories	
Classification Name	Handpiece, Direct Drive, Ac-Powered	
Regulation Number	872.4200	
Product Code(s)	EKX	
Legally Marketed Predicate Devices		
Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K181888	Osstell Beacon	EKX
K143445	Tellos ISQ Buddy	EKX
Device Description Summary		
The ChecQ is a dental implant stability analyzer comprising a main unit and a charging cradle that uses Resonance Frequency Analysis (RFA) to measure implant stability non-invasively. It works with the ChecQPEG, which attaches to the dental implant, and measures stability by analyzing resonant frequencies generated by magnetic field stimulation from the probe tip. The stability result is displayed on the main unit's screen as an Implant Stability Quotient (ISQ), ranging from 1 to 99. The RFA method evaluates by applying transverse force to the implant using magnetism, measuring movement, and analyzing the resulting resonance frequency. The resonance frequency depends on the bone-implant gap and is calculated using a formula, with values expressed as ISQ scores (1-99) for clinical interpretation. The ChecQ mechanism converts voltage pulses generated by the DAC of the MCU into magnetic pulses, which induce vibrations in the ChecQPEG magnets. The device captures the free vibrations as magnetic pulses, processes them through an FFT to extract the natural frequency, and calculates the ISQ value based on this frequency.		
Intended Use/Indications for Use		
ChecQ is indicated for use in measuring the stability of implants in the oral cavity and maxillofacial region.		
Indications for Use Comparison		

The ChecQ has same intended use of the predicate device currently being marketed, and there is no significant difference between two devices that would adversely affect the use.

Technological Comparison

The device description, software validation, performance testing, electromagnetic compatibility testing, sterilization validation, and biocompatibility assessment demonstrate the substantial equivalence of the subject device to the identified predicate device. The testing and documentation provided to support substantial equivalence of this device has been performed in accordance with the following standards:

- ANSI AAMI ES 60601-1:2005
- IEC 60601-1-2
- IEC 60601-1-6
- IEC 80601-2-60
- IEC 62366-1
- IEC 62133-2
- ISO 17665-1
- IEC 62304
- ANSI AAMI ST79
- ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-23
- ISO 7405

Therefore, conclusions drawn from testing demonstrate that ChecQ is substantially equivalent in performance to the predicate devices of K181888.

Non-Clinical and/or Clinical Tests Summary & Conclusions

The technological comparison and non-clinical testing of the “ChecQ” and “ChecQPEG” devices have been thoroughly evaluated through self-established test methodologies to ensure their performance and safety. There is no established test standard for these tests; however, they were conducted based on ISO 13485:2016 to ensure compliance with regulatory and quality requirements.

The ChecQ dental implant stability analyzer underwent comparative testing against the predicate device, Osstell Beacon, to assess its accuracy. The self-test methodology involved multiple measurements using standardized test jigs, and accuracy was determined based on the difference between the average values obtained from ChecQ and Osstell Beacon under the same test conditions. The results confirmed that ChecQ exhibited equivalent performance, establishing its functional equivalence with the predicate device.

The ChecQPEG also underwent multiple tests to verify its design and mechanical properties. The dimensional test confirmed that the manufactured parts met the required specifications. The locking and removal torque force test validated the device's stability and usability when attached to an implant fixture. The ISQ (Implant Stability Quotient) measurement test demonstrated the device’s reliability in assessing implant stability under simulated clinical conditions. Additional testing was conducted to evaluate the potential effects of the barrier sleeve on ISQ measurements, confirming that the presence of the barrier sleeve did not impact measurement accuracy.

These tests provide comprehensive verification of ChecQ and ChecQPEG's substantial equivalence to predicate devices. The results substantiate their compliance with international standards, demonstrating their suitability for clinical use and regulatory approval.