April 3, 2023

Shinhung Company Ltd
℅ Dave Kim
Medical Device Regulatory Affairs
Mtech Group
7505 Fannin St. Suite 610
Houston, Texas 77054

Re: K213749
Trade/Device Name: G7, Dental Operative Unit and Accessories
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit And Accessories
Regulatory Class: Class I, reserved
Product Code: EIA
Dated: March 6, 2023
Received: March 6, 2023

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 (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 -S

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)*
K213749

Device Name
G7 Dental System

Indications for Use *(Describe)*
The G7 Dental System and accessories 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, vacuum and electricity to allow the dental practitioner an intuitive control center for all common and normal patient treatment procedures performed in the dental operatory.

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
K213749

510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510k summary prepared: 3/17/2022

I. Submitter

Submitter's Name :	Shinhung Co., Ltd.
Submitter's HQ Address:	Shinhung Bldg, 450, Cheongpa-ro, Jung-gu, Seoul, 100-858, Korea
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Submitter's Telephone:	+82 (2) 6366-2175
Contact person:	Mr. Sam Su Kyong <sskyong@shinhung.co.kr> / RA Manager
Official Correspondent: (U.S. Designated agent) Address: Telephone:	Dave Kim (davekim@mtech-inc.net) Mtech Group 7505 Fannin St. Ste 610, Houston, TX 77054 +713-467-2607

II. Subject Device

Trade/proprietary name	:	G7
Regulation Name	:	Dental Operative Unit and Accessories
Regulation Number	:	21 CFR 872.6640
Product Code	:	EIA
Regulatory Class	:	Class I

Prescription Use.

III. Predicate Device

510(k) Number	:	K151996 (Jan. 22, 2016)
Primary Manufacturer	:	SHINHUNG. CO,.LTD
Device Name	:	TAURUS C1
Regulation Name	:	Dental Operative Unit and Accessories
Regulation Number	:	21 CFR 872.6640
Product Code	:	EIA
Regulatory Class	:	Class I

Prescription Use

This predicate has not been subject to a design-related recall.

IV. Reference Device

510(k) Number	:	K032756 (Dec. 04, 2003)
Primary Manufacturer	:	A-DEC, Inc
Device Name	:	A-DEC 532/533
Regulation Name	:	Dental Operative Unit and Accessories
Regulation Number	:	21 CFR 872.6640
Product Code	:	EIA
Regulatory Class	:	Class I

Prescription Use

V. Device Description

The G7 dental chair with operative unit is a dental chair with an operative unit attached for patient

to sit during the dental diagnosis, treatment and /or operation. The dental chair has adjustable headrest, backrest, seat height and armrests. The proposed device also consists of dentist table with instrument holders, assistant table, water unit, arm system, cuspidor (spittoon), dental light and foot control. The instrument holder includes a 3-way syringe and salvia ejector supplied by DCI which are cleared by FDA (K151987).

VI. Indications for Use

The G7 dental chair with operative unit is 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, vacuum and electricity to allow the dental practitioner an intuitive control center for all common and normal patient treatment procedures performed in the dental operatory.

VII. Comparison of Technological Characteristics with the Predicate Device

Model		**TAURUS C1 (K151996)**	**G7 (K213749)**
	Indications for Use	The TAURUS C1 Dental System and accessories 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, vacuum and electricity to allow the dental practitioner an intuitive control center for all common and normal patient treatment procedures performed in the dental operatory.	The G7 dental chair with operative unit is 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, vacuum and electricity to allow the dental practitioner an intuitive control center for all common and normal patient treatment procedures performed in the dental operatory.
	Construction	CHAIR / UNIT / DOCTOR TABLE /ASSISTANT TABLE / OPERATING LIGHT / FOOT CONTROL / STOOL	CHAIR /UNIT/ DOCTOR TABLE /ASSISTANT TABLE / OPERATING LIGHT / FOOT CONTROL / STOOL
	Power Supply	AC110V/115V, 50/60Hz	AC110V/115V, 50/60Hz

	Power Shock Protection	Class l	Class l
	Electric Protection	B Type	B Type
	EMC Standard	EN 60601-1-2	EN 60601-1-2
		IEC 61000-3-2	IEC 61000-3-2
		IEC 61000-3-3	IEC 61000-3-3
	Dental units Standard	ISO 7494-1 ISO 7494-2	ISO 7494-1 ISO 7494-2
	Dental unit& chair particular standard	-	IEC 80601-2-60
	Safety Standard	IEC 60601-1	IEC 60601-1
	Chair Operating system	Hydraulic system	Hydraulic system
Description	UNIT/CHAIR form type	Over-arm Contour type	Over-arm Contour type
	Inlet Air Pressure (Mpa)	0.6 ~ 0.78MPa	0.6 ~ 0.78MPa
	Inlet Water Pressure (Mpa)	0.2 ~ 0.59MPa	0.2 ~ 0.59MPa
	Allowable Patient Load	150 Kgf	150Kgf
	Vacuum system	Central Vacuum system or Air Vacuum system	DCI vacuum system with HVE and saliva ejectors (K151987)
	Flushing system	N/A	Included
	Water treatment with ICX tablet	N/A	Included
	3-Way Syringe	Adjusting the Water / Air / Spray function in the syringe	Adjusting the Water / Air / Spray function in the syringe with DCI tip (K151987)
	Vacuum syringe tip	Disposable tip	Not provided
	Vacuum syringe	POLY AMID, Durr	Aluminum, DCI
	Saliva-ejector	POLY AMID, Durr	Aluminum, DCI

	Low-speed / High-speed handpiece	Not provided	Not provided
	Scaler	Piezon kit, EMS	Piezon kit, EMS
	Cuspidor	Spittoon bowl / Rinsing pipe / Tumbler filler	Spittoon bowl / Rinsing pipe / Tumbler filler
	Water System	City Water / Distilled Water	City Water / Distilled Water
Operating Light	Type	Halogen (Shin Hung)	EDI LED
	Light head structure	3-axis head adjustment method	3-axis head adjustment method
	ON/OFF Control	Auto and manual ON/OFF	Auto and manual ON/OFF
	Brightness control	2 stage control	Continuous control
	Light pattern	130mmX70mm @ 700mm	130mmX70mm @ 700mm
Dental Chair	Loading Capacity	150kgf	150kgf
	Movement Range (Chair)	530 ~825mm(± 20 ㎜)	400 ~760mm(± 20 ㎜)
	Movement Range (Backrest)	0° ~ 63° (± 3°)	0° ~ 70° (± 3°)
	Headrest	Double-articulating headrest	Double-articulating headrest
	Table arm	Manual system	Air brake system
	Safety switch function	BACKREST and auxiliary arm, 2 safety switches	Rink cover and swing cover safety switch, emergency stop button located on the back of the chair seat, 3 safety switches.
		The safety switch stops the chair operation.	The safety switch stops the chair operation.
	Programmable chair position	Programmable chair position: Total 5 positions	Programmable chair position: Total 5 positions
Delivery system	Handpiece holder	6 integrated rotation type holder	6 integrated rotation type holder
	Handle	Fixed handle	Fixed handle
	Touchpad	Membrane panel	Membrane Panel
	Handpiece water and air cooling	Manually adjustable handpiece water / air cooling	Manually adjustable handpiece water / air cooling.

	Flexarm tension	Control the tension to adjust the shift of TABLE ARM rotation.	Control the tension to adjust the shift of TABLE ARM rotation.
Accessories	Instrument holders	HVE, SE, 3-WAYsyringe attached	HVE, SE, 3-WAYsyringe attached
	Foot control	Standard, all-in-one	Standard, all-in-one,
Support center	Cuspidor	Attach/detachable GLASS disassemble for cleaning.	Magnetic cuspidor disassemble for cleaning
	Solids collector	Equipped	Equipped
	Distilled water reservoir	Equipped	Equipped
	Cup water system	Automatic and manual water supply system.	Automatic and manual water supply system.
		Watering time can be set by the user.	Watering time can be set by the user.
Operation Method	Control panel / Assistant control panel / Foot controller		

VIII. Comparison of Technological Characteristics with the Reference Device

Model		**A-DEC 532/533 (K032756)**	**G7 (K213749)**
	Indications for Use	The A-dec 532/533 Delivery System Dental Unit and accessories 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, vacuum and electricity to allow the dental practitioner an intuitive control center for all common and normal patient treatment procedures performed in the dental operatory.	The G7 dental chair with operative unit is 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, vacuum and electricity to allow the dental practitioner an intuitive control center for all common and normal patient treatment procedures performed in the dental operatory.

	Construction	CHAIR / UNIT / DOCTOR TABLE /ASSISTANT TABLE / OPERATING LIGHT / FOOT CONTROL / STOOL	CHAIR /UNIT/ DOCTOR TABLE /ASSISTANT TABLE / OPERATING LIGHT / FOOT CONTROL / STOOL
	Vacuum syringe	Aluminum, DCI	Aluminum, DCI
	Saliva-ejector	Aluminum, DCI	Aluminum, DCI
	Flushing system	After each patient treatment, discharge water from the tubes of all handpieces for 20 to 30 seconds by using the flushing system. The flush switch is located at the bottom left of the doctor's table. Pull the flush switch and hold it until the waste is completely drained from the tubing. When only air comes out, release the flush switch.	After each patient treatment, discharge water from the tubes of all handpieces for 20 to 30 seconds by using the flushing system. The flush switch is located at the bottom left of the doctor's table. Pull the flush switch and hold it until the waste is completely drained from the tubing. When only air comes out, release the flush switch.
	Water treatment with ICX tablet	A-dec ICX tablets are specially formulated to maintain dental unit waterlines and prevent accumulation of odor and foul taste bacteria. Maintains dental unit waterline effluent ≤10 CFU/ml.	A-dec ICX tablets are specially formulated to maintain dental unit waterlines and prevent accumulation of odor and foul taste bacteria. Maintains dental unit waterline effluent ≤10 CFU/ml.

The technological characteristics between the proposed device and the predicate device are similar physically and technically. Both the subject device, the predicate device and the reference device share the same indications for use as well as equivalent material composition, fundamental engineering technology, principles of operation and basic design. Moreover, G7, the subject device, and A-DEC 532/533, the reference device (K032756) share the same vacuum syringe, saliva-ejector, flushing system and the water treatment regime.

IX. PERFORMANCE DATA

The G7 dental chair with operative unit complies with the following performance standards.

Non Clinical testing:

ISO 10993-1:209/(R) 2013 Biological evaluation of medical devices—Part1: Evaluation and

testing within a risk management process.
IEC 60601-1 Test for Medical Electrical Equipment was performed for General Requirements for basic safety and essential performance. The requirements of specified standards were fulfilled.
IEC 60601-1-2 Test for Medical Electrical Equipment was performed for General Requirements for basic safety and essential performance (collateral standards: electromagnetic compatibility. The requirements of specified standards were fulfilled.
IEC 80601-2-60 Test for Particular requirements for the basic safety and essential performance of dental equipment. The requirements of specified standards were fulfilled.
ISO 7494-1 Test was performed for general requirements and test methods: Pass
ISO 7494-2 Test was performed for general requirements for water and air supply: Pass

Software Verification and Validation Testing
Firmware for G7 includes PCB Foot Blu Slave MPU and Master MPU board to receive and transmit wireless foot controller signals. Software verification and validation testing were conducted and documented 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, since a failure or latent flaw in the software would not directly result in serious injury or death to the patient or operator.

All test results were satisfactory.

X. 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 Shinhung Co, Ltd. concludes that The G7 dental operative unit is substantially equivalent to TAURUS C1, the predicate device, and A-DEC 532/533, the reference device, in indications for use, material composition, fundamental engineering technology, the principle of operation and basic design.