



Food and Drug Administration
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January 22, 2016

Shinhung Company, Ltd.
c/o Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
Houston, Texas 77025

Re: K151996

Trade/Device Name: Taurus C1
Regulation Number: 21 CFR 872.6640
Regulation Name: Operative Dental Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: December 9, 2015
Received: December 15, 2015

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina Kiang -
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for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,

Respiratory, Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Indications for Use

510(k) Number (if known)

K151996

Device Name

TAURUS C1

Indications for Use (Describe)

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 operator.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional 510(k) Summary

This 510(k) summary is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510k summary prepared: December 10, 2015

I. SUBMITTER

Submitter's Name : Shinhung Co., Ltd.
Submitter's HQ Address: Shinhung Bldg, 450, Cheongpa-ro, Jung-gu,
Seoul, 100-858, Korea
Factory Address: 42-25, 27beon-gil, Dongsan-ro, Danwon-gu,
Ansan-si, Gyeonggi-Do, 425-852 Korea

Submitter's Telephone: +82(2)6366-2124
Contact person: Sky Shin(sky@shinhung.co.kr) / Manager

Official Correspondent: Dave Kim (davekim@mtech-inc.net)
(U.S. Designated agent)
Address: 8310 Buffalo Speedway, Houston, TX 77025
Telephone: +713-467-2607
Fax: +713-583-8988

II. DEVICE

Trade/proprietary name : TAURUS C1
Common or Usual Name : Dental Chair and Units
Regulation Name : Dental Operative Unit and Accessories
Regulation Number : 21 CFR 872.6640 (Product Code: EIA)
Regulatory Class : I Class
Prescription Use.

III. PREDICATE DEVICE

Primary Manufacturer : A-DEC, INC
Device Name : A-DEC 200 DENTAL SYSTEM
510(k) Number : K102234 (Decision Date – Jan. 13, 2012)
Regulation Name : Dental Operative Unit and Accessories
Regulation Number : 21 CFR 872.6640 (Product Code: EIA)
Regulatory Class : I Class

Prescription Use

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

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

TAURUS C1 is a dental chair and units to be used to take for diagnosis and therapy of patients. It consists of the main unit and accessories.

The dental chair is used for patient to sit during the dental diagnosis, treatment and /or operation. The dental unit consists of patient chair, dentist table with instrument holders, assistant table, water unit, arm system, cuspidor (spittoon) and dental light. The dental unit system is used by trained dentists and /or dental assistants to supply air, water, vacuum and electrical power to dental devices and accessories to allow the dental practitioner an intuitive control center for all common and normal patient treatment procedures performed in the dental operator.

V. 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Model		A-dec 200 (K102234)	TAURUS C1 for 510K
Indications for Use		The A-dec 200 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 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.
	Construction	CHAIR / UNIT / DOCTOR TABLE / ASSISTANT TABLE / OPERATING LIGHT / FOOT CONTROLLER / STOOL	CHAIR / UNIT/ DOCTOR TABLE / ASSISTANT TABLE / OPERATING LIGHT / FOOT CONTROLLER / STOOL
	Power Supply / Frequency	AC100V/110V/120V, AC210/220/230V , 50/60Hz	AC100V/110V/115V, AC210/220/230V, 50/60Hz
	Power Shock Protection	Class 1	Class 1
	Electric Protection	B Type	B Type

Description (Comparative testing confirmed equivalence to the noted predicate)	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 Patient chair Standard	ISO 6875	ISO 6875
	Safety Standard	EN 60601-1	EN 60601-1
	Chair Operating system	Hydraulic system	Hydraulic system
	UNIT/CHAIR form type	Over-arm Contour type	Over-arm Contour type
	Vacuum system	Central 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.
	Cuspidor(Spittoon)	Spittoon bowl / Rinsing pipe / Tumbler filler	Spittoon bowl / Rinsing pipe / Tumbler filler
	Water System	City Water / Distilled Water	City Water / Distilled Water
	Comparative testing confirmed equivalence to the noted predicate		
Operating Light	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
	Headrest	Double-articulating headrest	Double-articulating headrest
	Safety switch function	Chair lift arm and auxiliary arm, 2 safety switches	Chair lift arm and auxiliary arm, 2 safety switches
		The safety switch stops the chair operation.	The safety switch stops the chair operation.

	Programmable chair position	Programmable chair position: Total 4 positions	Programmable chair position: Total 5 positions
Delivery system	Handpiece holder	5 angle adjustable holders	6 integrated rotation type holder
	Handle	Adjustable 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 flexarm rotation flow.	Control the tension to adjust the shift of TABLE ARM rotation.
Accessories tools	Accessories holder	HVE, SE, 3-WAY syringe attached	HVE, SE, 3-WAY syringe attached
	Holder structure	Rotation and individual holder	Fixed, one-piece holder
Support center	Cuspidor	Self-contained 2 liter water bottle system	Attach/detachable GLASS, disassemble for cleaning
	Solids collector	Equipped	Equipped
	Distilled water reservoir	Equipped	Equipped
	Cup water system	Manual water system Press the cupfill button for a timed operation. Press and hold the cupfill button for manual operation.	Automatic and manual water system. Place the cup at the specified location for a timed operation.
Accessories attached to the device:	handpiece / Low speed handpiece / Scaler / Curing light / Dental Chair / 3-way syringe		
Operation Method	Control panel / Assistant control panel / Foot controller		

VII. PERFORMANCE DATA

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

Biocompatibility testing:

TAURUS C1 dental operative unit and accessories use the materials already cleared for patient contact components such as patient chair seat, arm rest, 3 way syringe,

vacuum syringe, and saliva ejector which are similar to the predicate device.

Non Clinical testing:

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.

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

ISO6875 test was performed for general, electrical, and mechanical requirements: Pass

VIII. CONCLUSIONS

There are no significant differences between the TAURUS C1 and the predicate device. .

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 TAURUS C1 is substantially equivalent in comparison with Adec-200, the predicate device as described herein.