DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 1, 2016

DCI
% Mr. Robert Bellingham
Quality & Regulatory Manager
305 N. Springbrook Rd.
Newberg, Oregon 97132

Re: K151987
Trade/Device Name: DCI Edge Dental Chair with Operative Unit
Regulation Number: 21 CFR 872.6250
Regulation Name: Dental Chair and Accessories
Regulatory Class: I
Product Code: KLC, EIA
Dated: May 2, 2016
Received: May 2, 2016

Dear Mr. Bellingham:

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" (21 CFR 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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151987

Device Name

DCI Edge Dental Chair with operative unit

Indications for Use *(Describe)*

The DCI Edge Dental Chair with operative unit is a device intended to position the patient in such a manner to provide to the dental practitioner visual and manual access to the oral cavity. This device should provide for the ergonomic necessities of most patients, both adults and children, throughout its range of movement. The device shall also be the means of supporting delivery systems for the purpose of standard dental procedures.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K151987
510(k)
Summary
DCI Edge Dental Chair with Operative Unit

1 Sponsor

Dental Components Inc.
305 N. Springbrook Road
Newberg, Oregon 97128
Telephone: 503-537-2431
Date Prepared: May 31, 2016

2 Device Name

Proprietary Names: DCI Edge Dental Chair with Operative Unit
Common/Usual Name: Chair, Dental with Operative Unit
Classification: Chair, dental, with operative unit
Regulation Number: 21 CFR 872.6250
Class: 1
Product Code: KLC
Secondary Product Code: EIA
Establishment Registration Number: 3029780

3 Predicate Device

Foshion Chair Mounted Dental Unit (K071353)

4 Intended Use

The DCI Edge Dental Chair with operative unit is a device intended to position the patient in such a manner to provide to the dental practitioner visual and manual access to the oral cavity. This device should provide for the ergonomic necessities of most patients, both adults and children, throughout its range of movement. The device shall also be the means of supporting delivery systems for the purpose of standard dental procedures.

5 Device Description and Function

The DCI Edge Chair with Operative Unit is a dental chair with an operative unit attached. There are three main parts to the proposed device: a dental chair, dental light and dental unit. The dental chair has adjustable headrest, backrest, seat height and armrests. The dental chair unit consists of a floor box to which are attached a number of operative units: lights, cuspidor, cup filling device, control panel, and foot control. The instrument panel also includes a 3-way syringe and salvia ejector.

6 Level of Concern

The software was determined to be of a moderate level of concern. The software controls the movement of the dental chair, and it is preprogrammed and activated by the push of a button. The chair then moves slowly up and down, and the backrest moved slowly from an upright or a reclined position. The movement is very slow and the movement is limited by a stop sensor and mechanical hard stop. There are sensors and hard stops to prevent the chair from going beyond its pre-programmed range.

7 Technological Characteristics Summary

The technological characteristics between the predicate and proposed device are similar physically and technically. While the wording of the Indications for Use differs, both the subject and predicate devices share the same intended use, as well as equivalent material composition, fundamental scientific technology, principles of operation, and basic design. The predicate device does offer several accessories as standard, such as x-ray viewer and dental handpiece. The DCI Edge chair does not offer these as standard. However, the intended use and the fundamental scientific technology are still the same. The x-ray viewer and dental handpieces are available from other companies as aftermarket devices.

PARAMETER	DCI EDGE CHAIR W/OPERATIVE UNIT (K151987)	DCI DENTAL UNIT (K944271)	FOSHION DENTAL CHAIR W/OPERATIVE UNIT (K071353)
Intended Use	The DCI Edge Dental Chair with operative unit is a device intended to position the patient in such a manner to provide to the dental practitioner visual and manual access to the oral cavity. This device should provide for the ergonomic necessities of most patients, both adults and children, throughout its range of movement. The device shall also be the means of supporting delivery systems for the purpose of standard dental procedures.	The DCI Dental Unit is intended to supply power and serve as a base for dental devices and accessories. The product includes a dental unit, 3-way syringe and air foot control. The unit is intended for use in the dental office or clinic and is used by trained dentists and/or technicians and assistants. It can be attached to a chair or stand alone.	The Foshion Chair Mounted Dental Unit is intended to supply power and serve as a base for dental devices and accessories. The product includes a dental chair, operating light x-ray viewer, control panel, low and high speed turbine handpieces, 3- way syringe and air foot control. The unit is intended for use in the dental office or clinic and is used by trained dentists and/or dental technicians and assistants.
Features			
Seat and backrest positioning	Pre-programmed settings.	N/A	Pre-programmed settings.
Multiple Handpiece Automatic Control System	Three handpiece controls are standard, up to five handpieces optional. Handpieces are not sold with the unit.	Three handpiece controls are standard, up to five handpieces optional. Handpieces are not sold with the unit.	Three handpiece controls are standard, up to five handpiece optional. Unit is sold with handpieces.
Water Control System for Handpieces and Syringes	Non-retracting water system for handpieces and syringes. Retracting available with check-valve.	Non-retracting water system for handpieces and syringes. Retracting available with check-valve.	Non-retracting water system for handpieces and syringes. Retracting available with check-valve.
3-Way Syringe	3-Way syringe with quick disconnect tip and autoclavable tips standard.	3-Way syringe with quick disconnect tip and autoclavable tips standard.	3-Way syringe with quick disconnect tip and autoclavable tips standard.

Instrument Holders	Multiple position holder.	Multiple position holder.	Multiple position holder.
Assistant Holders	Multiple position holder.	Multiple position holder.	Multiple position holder.
Gravity Drain Cuspidor	Cuspidor available.	Cuspidor available.	Cuspidor available.
Mounting	Chair and cart.	Chair and cart.	Chair and cart.
Vacuum System	HVE and saliva ejectors available.	HVE and saliva ejectors available.	HVE and saliva ejectors available.
Foot Control	Standard.	Standard.	Standard.
Utility Box with Air and Water Shut-off, Regulators and Filters	Standard.	Optional w/Chair	Standard.
Control Pad for Chair Movement and Light	Standard	Optional w/Chair	Standard
Heated Water Supply	Available.	Optional w/Chair	Available.
Dental Light	Available.	Available	Available.
Turbines	Can be added.	Can be added	Standard
Upholstery	Standard	Standard if ordered w/Chair	Standard
Arm Rest	Standard	Standard if ordered w/Chair	Standard
Materials			
Construction	Metal structural support, sheet metal, plastic covers. Details contain in product manual.	Metal structural support, sheet metal plastic covers.	Metal structural support, sheet metal, plastic covers.

8 Non Clinical Testing

The DCI Edge Dental Chair with Operative Unit complies with the following performance standards:

- ISO 14971 Second Edition 2007-03-01 Medical devices – Application of risk management to medical devices.
- AAMI ANSI ISO 10993-1:209/(R) 2013 Biological evaluation of medical devices—Part1: Evaluation and testing within a risk management process.
- ANSI/AAMI ES60601-1:2005/(R)2012 Issued: 2012/01/17 Medical Electrical Equipment—Part 1: General requirements for basic safety and essential performance with C1:2009 (R)2012 and A2:2010/(R)2012
- ISO 60601-1-2:2007 Medical electrical equipment –Part1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility-Requirements and test.
- IEC 62366 Edition 1.1 – Medical devices-Application of usability engineering to medical devices.
- IEC 80601-2-60:2012 – Medical electrical equipment – Part 2-60: Particular requirements for basic safety and essential performance of dental equipment.

9 Conclusion

DCI, ITL has demonstrated that, for the purposes of FDA's regulation of medical devices, the DCI Edge Dental Chair with Operative Unit is substantially equivalent to the predicate devices in intended use, material composition, fundamental scientific technology, principles of operation, and basic design.