K082207

510(k) SUMMARY

Cadent's OrthoCAD iQ

OCT 23 2009

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Cadent, Inc.
640 Gotham Parkway
Carlstadt, NJ 07072

Phone: (201) 842-0800
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Contact Person: Edward J. Sitar

Date Prepared: October 21, 2009

Trade Name of Device

OrthoCAD iQ

Common or Usual Name of Device

Accessory to Orthodontic Brackets

Classification Name, Classification Regulation, and Product Code(s)

Classification Name: Orthodontic Plastic Brackets

Classification Regulation: 21 C.F.R. 872.5470

Product Codes: DYW (Orthodontic Plastic Bracket), NJM (Orthodontic Ceramic Bracket), and EJF (Orthodontic Metal Bracket)

Predicate Devices

Cadent Inc.'s OrthoCAD System
Align Technologies, Inc.'s Invisalign System
OraMetrix, Inc.'s SureSmile System

Intended Use / Indications for Use

OrthoCAD iQ is a computer-guided system intended for use as an aid in orthodontic treatment planning for use by dental professionals trained in orthodontic treatment

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including radiographic analyses and treatment planning. *OrthoCAD iQ* is intended for use with commercially-available brackets and wires that apply continuous gentle force to reposition the teeth. It also uses indirect bonding trays to affix the brackets in position.

Technological Characteristics

The device consists of the following components and accessories: proprietary software that calculates the position of dental brackets based on the dental impressions and treatment plan supplied by the patient's orthodontist, commercially-available metal, plastic, or ceramic brackets supplied by the orthodontist for that patient, a camera wand with a light curing feature, and customized indirect bonding trays containing the brackets, which are in a hard plastic case. The device does not include the adhesive that affixes the brackets to the teeth or the wires that are used with the brackets to form braces.

Principles of Operation

OrthoCAD iQ's software creates a computer model of the patient's dentition based on a stone model. The orthodontist uses this computer model to determine the placement of dental brackets to achieve the intended repositioning of the teeth. Cadent, using the camera wand, manufactures an indirect bonding tray with the brackets in the positions prescribed by the orthodontist. The orthodontist uses the indirect bonding trays to place the brackets and a commercially-available dental adhesive to affix them to the patient's teeth.

Performance Data

Testing has demonstrated the electrical safety of the OrthoCAD iQ. Software verification and validation confirmed the performance of the device. Clinical cases demonstrate that it functions as intended.

Substantial Equivalence

OrthoCAD iQ has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. All of these devices create customized dental appliances based on computer models of the patient's pre-treatment and post-treatment dentition. The minor technological differences between this device and its predicate devices raise no new issues of safety or effectiveness. Thus, the OrthoCAD iQ is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Cadent, Incorporated
C/O Ms. Laurie Clarke
King & Spalding, L.L.P.
1700 Pennsylvania Avenue, North West
Washington, DC 20006-4706

OCT 23 2009

Re: K082207
Trade/Device Name: OrthoCAD iQ
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
8Regulatory Class: II
Product Code: DYW, NJM, EJF
Dated: October 19, 2009
Received: October 19, 2009

Dear Ms. Clarke:

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082207

Device Name: OrthoCAD iQ

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Prescription Use ____x___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulky for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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