

K121524

510(k) Summary



AUG 9 2012

SYBRON DENTAL SPECIALTIES

Submitter:

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Date Summary Prepared: May 2012

Device Name:

- Trade Name – *Insignia*
- Common Name – Accessory to Orthodontic Brackets
- Classification Name – Orthodontic Plastic Bracket, per 21 CFR § 872.5470
- Product Codes - Orthodontic Plastic Bracket (DYW), Orthodontic Ceramic Bracket (NJM) and Orthodontic Metal Bracket (EJF)

Devices for Which Substantial Equivalence is Claimed:

- *OrthoCAD iQ*, Cadent, Inc., K082207

Device Description:

Principles of Operation

The *Insignia* software creates a computer model of the patient's dentition based on either a stone model or impression of the patient's dentition. *Insignia* operators and the orthodontist use this computer model to determine the placement and/or modification of dental brackets to achieve the intended repositioning of the teeth. Ormco then manufactures foam bracket placement jigs to position the brackets on the patient's teeth in specific positions prescribed by the orthodontist. The orthodontist uses the foam jigs to place and secure the brackets with a commercially-available dental adhesive.

Technological Characteristics

Insignia consists of the following components and accessories:

- 1) Proprietary software that calculates the position of dental brackets based on the dental impressions and treatment plan supplied by the patient's orthodontist.
- 2) Commercially-available metal, plastic, or ceramic brackets and/or individually modified metal brackets.
- 3) Patient-specific foam bracket placement jigs to affix the brackets in position.
- 4) Either commercially-available or patient-specific shaped traditional archwires.

The device does not include the adhesive that affixes the brackets to the teeth.

Indications for Use:

The *Insignia* Orthodontic System is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients, using appliances individualized for the orthodontic patient.

Summary of Technological Characteristics:

Insignia is substantially equivalent to another legally marketed device in the United States.

Insignia functions in a manner similar to and is intended for the same use as *OrthoCAD iQ* that is currently marketed by Cadent, Inc.

Features	<i>Insignia</i>	<i>OrthoCad IQ</i>
Intended Use	<i>Insignia</i> is a computer-guided system intended for use as an aid in orthodontic treatment planning for use by dental professionals trained in orthodontic treatment including radiographic analyses and treatment planning. <i>Insignia</i> is intended for use with commercially-available and/or individually modified brackets and wires that apply continuous gentle force to reposition the teeth. It also uses patient-specific foam placement jigs to affix the brackets in position.	<i>OrthoCad IQ</i> is a computer-guided system intended for use as an aid in orthodontic treatment planning for use by dental professionals trained in orthodontic treatment including radiographic analyses and treatment planning. <i>OrthoCad IQ</i> is intended for use with commercially-available brackets and wires that apply continuous gentle force to reposition the teeth. It also uses molded thermoplastic trays to affix the brackets in position.
Sequence of Treatment Plan	<ul style="list-style-type: none"> • A 3D digital model is created based on a stone model or a patient's dental impression 	<ul style="list-style-type: none"> • A 3D digital model is created from a patient's impression

Features	Insignia	OrthoCad IQ
	<ul style="list-style-type: none"> • A 3D end-of-treatment outcome model is generated • The 3D model is sent to the orthodontist for review • Foam bracket placement jigs are manufactured to position the brackets on the patient's teeth as prescribed by the orthodontist • Brackets are adhered to the patient's teeth 	<ul style="list-style-type: none"> • A 3D end-of-treatment outcome model is generated • The 3D model is sent to the orthodontist for review • Customized trays are created with each bracket in the ideal position to achieve the desired outcome. • Brackets are adhered to the patient's teeth
Bracket Material	Stainless Steel / Ceramic / Plastic	Stainless Steel / Ceramic / Plastic
Archwire Material	Stainless Steel / Nickel Titanium / Beta Titanium	Stainless Steel / Nickel Titanium / Beta Titanium
Positioning Device Material	Plastic foam	Thermoformed plastic
Mode of Use	Either patient-specific (individually modified) or standard appliances are fixed to the patient's teeth using patient-specific foam placement jigs. Patient-specific archwires of traditional metallurgy are provided. The appliances are fixed to the teeth with commercially available adhesives.	Standard appliances are fixed to the patient's teeth using thermoformed trays. Archwires of traditional metallurgy are selected. The appliances are fixed to the teeth with commercially available adhesives.
Description of Appliance Placement	Affixed and removed by clinician	Affixed and removed by clinician
Manufacturing Method	Final desired arrangement of teeth, brackets, wires and jigs are designed with the guidance of computer software using 3-dimensional models of the patient. In-office software allows the clinician to review, alter and approve desired result and appliances. Software generates code that drives machinery to manufacture the appliances.	Final desired arrangement of teeth is designed with the guidance of computer software using 3-dimensional models of the patient. In-office software allows the clinician to select, review, alter and approve desired result and appliances

Non-Clinical Test Data:

Biocompatibility studies (Cytotoxicity, Irritation and Sensitization) have been completed which demonstrate that the *Insignia* components including the bracket placement jig, the jig adhesive and the midline marker for the archwire, are safe for their intended use.

Additionally, the *Insignia* software has been successfully validated to confirm the performance of the device.

Clinical Test Data:

Clinical testing has not been conducted on this product.

Conclusion:

Based upon the biocompatibility studies, similar technological characteristics to the predicate device, and successful validation of the *Insignia* software, the performance of *Insignia* is deemed to be substantially equivalent to *OrthoCAD iQ*.



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

AUG 9 2012

ORMCO Corporation
C/O Sybron Dental Specialties, Incorporated
Ms. Wendy Garman
Director, Regulatory Affairs
1717 West Collins Avenue
Orange, California 92867

Re: K121524
Trade/Device Name: Insignia
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: DYW, NJM, EJF
Dated: July 27, 2012
Received: July 30, 2012

Dear Ms. Garman:

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 go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



Anthony D. Watson, B.S., M.S., M.B.A.
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): K121524

Device Name: *Insignia*

Indications For Use:

The *Insignia* Orthodontic System is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients, using appliances individualized for the orthodontic patient.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sina Paver

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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