DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Ormco Corporation
c/o Mr. Dave Yungvirt
Third Party Review Group, LLC
The Old Station House,
24 Lackawanna Place
Millburn, New Jersey 07041

July 18, 2017

Re: K171844
Trade/Device Name: Inspire ICE™ aka Inspire ICE™ Clear Brackets
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NJM
Dated: June 18, 2017
Received: June 20, 2017

Dear Mr. Dave Yungvirt:

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,

Mary S. Runner -A

Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Change Control Table, Change History

Change Control Table

Version	Document Author	Document Approver	Date Approved
1.00	Name, Title, Office	Name, Title, Office	MM/DD/YYYY

Complete Change Control Table (all versions) retained in SWIFT Docs.

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)*

TBD

Device Name

Inspire ICE™, aka Inspire ICE™ Clear Braces

Indications for Use *(Describe)*

Inspire ICE, a ceramic orthodontic bracket, is intended for use during orthodontic treatment of malocclusions. A malocclusion is imperfect positioning of the teeth when the jaws are closed.

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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SECTION 5. 510(k) SUMMARY K171844

For Inspire ICE (Ceramic Orthodontic Brackets)

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

1. **510(k) Submitter**……. Ormco Corporation
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4. **Date Prepared**…… May 15, 2017

5. **Device**
Proprietary Name……. Inspire ICE™, aka Inspire ICE™ Clear Braces
Classification Name …… Bracket, Ceramic Dental
Regulation Number ……..21 CFR 872.5470
Product Code ……NJM
Medical Specialty Panel……76 | Dental
Classification…….Medical Device, Class II

6. **Predicate Device**
Inspire ICE is substantially equivalent to American Orthodontics', Radiance Plus® brackets, K080749, product code NJM, cleared on August 4, 2008.

7. **Predicate Reference Device**
The Inspire ICE orthodontic ceramic bracket is the next generation of the original Vanish Orthodontic Bracket, K844067, cleared on November 23, 1984. The Vanish bracket is included in this 510(k) submission as a 'predicate reference'. Although the Inspire ICE bracket is substantially equivalent to the Vanish bracket, Vanish could not be declared as the predicate because it was cleared under Product Code EJF, Metal Orthodontic Brackets.

8. **Device Description**

Inspire ICE, is a single-use orthodontic bracket made from monocrystalline alumina. The brackets are intended for use during orthodontic treatment of malocclusions. A malocclusion is imperfect positioning of the teeth when the jaws are closed. After following standard office protocols for tooth preparation, the brackets are bonded to the teeth with an orthodontic adhesive or cement. An archwire is then threaded through the bracket's archwire slot and is held in place with a ligature tie. These ligatures are tightened, or ligated, around the 'wings' of the bracket and over the archwire. To aid in optimal teeth movement, the individual brackets can also be ligated to other brackets or other orthodontic devices. After the teeth have moved into their proper positions, the orthodontic / dental professional will remove the brackets with the Inspire ICE Debonding Pliers. This step is also known as debonding.

Accessory Used with Inspire ICE	Manufacturer of Accessory	Premarket Notification
Inspire ICE Debonding Pliers	Ormco 1332 S. Lone Hill Avenue Glendora, CA 91741 USA	Exempt from premarket notification requirements

9. **Indications for Use**

Inspire ICE, an orthodontic ceramic bracket, is intended for use during orthodontic treatment of malocclusions. A malocclusion is imperfect positioning of the teeth when the jaws are closed.

10. **Description of Safety and Substantial Equivalence**

Technological Characteristics

The designs of Inspire ICE are similar to the predicate American Orthodontics', Radiance Plus® (K080749), Product Code NJM, cleared on August 4, 2008 and to the reference predicate Vanish Orthodontic Bracket, K844067, Product Code EJF, cleared on November 23, 1984. All three are clear ceramic twin brackets, created from a single crystal of pure grown sapphire.

Non-Clinical Performance Data

Non-clinical performance data included testing results for Bond Strength, Tie Wing Strength and Torque Strength, as well as Biocompatibility and Stability testing. Along with internal test methods, the following applicable standards were utilized for the non-clinical performance testing:

- ISO 27020 Dentistry – Brackets and Tubes for use in Orthodontics
- ISO 10993-1:2009 Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process
- ISO 10993-2:2006 Biological evaluation of medical devices Part 2: Animal welfare requirements
- ISO 10993-3:2014 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-6:2007 Biological evaluation of medical devices Part 6: Tests for local effects after implantation
- ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2006 Biological evaluation of medical devices Part 11: Tests for systemic toxicity
- ISO 10993-12:2012 Biological evaluation of medical devices Part 12: Sample preparation and reference materials (available in English only)
- ISO 10993-17:2002 Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18:2005 Biological evaluation of medical devices Part 18: Chemical characterization of materials
- ISO 14971:2007 Medical Devices – Application of risk management to medical devices, Annex 1: Guidance on Risk Analysis Procedures for Biological Hazards

Predicate and Proposed Device Comparison

Element	Radiance Plus (Predicate Device)	Vanish (Predicate Reference)	Inspire ICE (Proposed Device)
510(k)	K080749	K844067	To be assigned
Trade Name	Radiance Plus	Vanish Orthodontic Bracket	Inspire ICE, aka Inspire ICE Clear Braces
Target Users	Licensed Orthodontic / Dental Professionals	Licensed Orthodontic / Dental Professionals	Licensed Orthodontic / Dental Professionals
Device Description	Radiance Plus is a single-use monocrystalline	Vanish is a single-use monocrystalline	Inspire ICE is a single-use monocrystalline

Element	Radiance Plus (Predicate Device)	Vanish (Predicate Reference)	Inspire ICE (Proposed Device)
	sapphire orthodontic twin bracket.	sapphire orthodontic twin bracket.	sapphire orthodontic twin bracket.
Indications for Use	Orthodontic brackets are prescribed for patients with teeth that are not normally positioned in the mouth. Orthodontic treatment is used to correct dental deficiencies and to improve the appearance of the patient.	Orthodontic bracket is intended for use by orthodontists to assist in restoring the natural occlusion of teeth.	Intended for use during orthodontic treatment of malocclusions. A malocclusion is the imperfect positioning of the teeth when the jaws are closed.
Common Name	Orthodontic Ceramic Bracket	Orthodontic Metal Bracket	Orthodontic Ceramic Bracket
Classification Name	Bracket, Ceramic, Dental	Bracket, Metal, Orthodontic	Bracket, Ceramic, Dental
Class	II	I	II
Product Code	NJM	EJF	NJM
Material	Alumina (Al_2O_3)	Alumina (Al2O3)	Alumina (Al_2O_3)
Clarity	Transparent	Transparent	Transparent
Bracket Design	1-Piece Base and Bracket Construction	1-Piece Base and Bracket Construction	1-Piece Base and Bracket Construction
Ligation	Non Self-Ligating	Non Self-Ligating	Non Self-Ligating
Manufacturing Method	Grinding	Grinding	Grinding
Hooks	Machined Hooks	Machined Hooks	Machined Hooks
In/Out	Unknown	.035” - .059”	.035” - .050”
Torque	+17° thru -22°	+17° thru -22°	+17° thru -22°
Angulation	Up to +10°	Up to +13°	Up to +13°
Rotation	Up to 4°	Up to 4°	Up to 4°

Element	Radiance Plus (Predicate Device)	Vanish (Predicate Reference)	Inspire ICE (Proposed Device)
Bracket Identification and Placement	Color Coded Visual Placement Aids (VPAs) Colored dot to indicate Upper/Lower, Left/Right	Water-Soluble Face Paint™ Identification System Colored dot to indicate Upper/Lower, Left/Right	Water-Soluble Face Paint™ Identification System Colored dot to indicate Upper/Lower, Left/Right
Material Composition for Bracket Identification and Placement	Unknown	Supplier's proprietary Red, Purple, Green, Yellow, Blue, Orange or Black water-soluble temporary ink/colorant*. **Per an independent accredited medical research service company, the finished device is considered to have met biological evaluation and risk assessment requirements.*	Supplier's proprietary Red, Purple, Green, Yellow, Blue, Orange or Black water-soluble temporary ink/colorant*. **Per an independent accredited medical research service company, the finished device is considered to have met biological evaluation and risk assessment requirements.*
Bracket Base	Quad Matte™ base that is intended to provide variable bond strength across different locations along the base	Ball-base technology that is evenly distributed and fused onto the bottom of the bracket which provides optimal bond strength between the bracket and tooth	Ball-base technology that is evenly distributed and fused onto the bottom of the bracket which provides optimal bond strength between the bracket and tooth
Single Use	Yes	Yes	Yes
Non-Sterile Packaging	Yes	Yes	Yes
Debonding Hand Instrument Accessory	Radiance Plus Debonding Pliers (REF: 001-343E) or Omega Ceramic Bracket Debonding Pliers (Sushi pliers REF: 001-301E)	ICE Debonding Plier (REF: 866-4020)	ICE Debonding Plier (REF: 866-4020)

Clinical Performance Data

Clinical performance testing has not been performed for Inspire ICE.

Conclusion as to Substantial Equivalence

Although there are semantic differences between the indications for use of Radiance Plus brackets (predicate device), Vanish brackets (predicate reference) and Inspire ICE brackets (proposed device), these differences do not change the indications. Therefore, the indication of use for Inspire ICE brackets is equivalent to the predicate device Radiance Plus (K080749) and predicate reference Vanish (K844067).

The Radiance Plus (predicate device), Vanish (predicate reference) and Inspire ICE bracket systems (proposed device) all offer a hand instrument accessory designed for bracket debonding.

The technological characteristics of Inspire ICE brackets are very similar to the predicate device Radiance Plus brackets (K080749) and the predicate reference Vanish brackets (K844067). Results of the nonclinical testing, demonstrate that Inspire ICE is as safe, as effective, and performs as well as the predicate devices in terms of the design, intended use, indications for use, manufacturing method, mechanical properties and biocompatibility. The information provided herein, demonstrates that Inspire ICE brackets are substantially equivalent to the legally marketed predicate device Radiance Plus brackets (K080749) and predicate reference Vanish brackets (K844067).