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

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<th>Version</th>
<th>Document Author</th>
<th>Document Approver</th>
<th>Date Approved</th>
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<tr>
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<td>Name, Title, Office</td>
<td>Name, Title, Office</td>
<td>MM/DD/YYYY</td>
</tr>
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Complete Change Control Table (all versions) retained in SWIFT Docs.
Indications for Use

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)

- [X] 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.

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Department of Health and Human Services
Food and Drug Administration
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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."
SECTION 5. 510(k) SUMMARY

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
   1717 W. Collins Avenue
   Orange, California 92867

2. **Contact**
   Tara Bonny
   Regulatory Affairs
   Phone: 909-962-5856
   Fax: 909-962-5694
   Email: Tara.Bonny@kavokerr.com

3. **Additional Contact**
   Wendy Garman
   Vice President, Regulatory Affairs
   Phone: 909-962-5666
   Fax: 909-962-5694
   Email: Wendy.Garman@kavokerr.com

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.

<table>
<thead>
<tr>
<th>Accessory Used with</th>
<th>Manufacturer of Accessory</th>
<th>Premarket Notification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspire ICE</td>
<td>Ormco</td>
<td>Exempt from premarket notification requirements</td>
</tr>
<tr>
<td>Inspire ICE Debonding Pliers</td>
<td>1332 S. Lone Hill Avenue Glendora, CA 91741 USA</td>
<td></td>
</tr>
</tbody>
</table>

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 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
- 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 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

<table>
<thead>
<tr>
<th>Element</th>
<th>Radiance Plus (Predicate Device)</th>
<th>Vanish (Predicate Reference)</th>
<th>Inspire ICE (Proposed Device)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>510(k)</strong></td>
<td>K080749</td>
<td>K844067</td>
<td>To be assigned</td>
</tr>
<tr>
<td><strong>Trade Name</strong></td>
<td>Radiance Plus</td>
<td>Vanish Orthodontic Bracket</td>
<td>Inspire ICE, aka Inspire ICE Clear Braces</td>
</tr>
<tr>
<td><strong>Target Users</strong></td>
<td>Licensed Orthodontic / Dental Professionals</td>
<td>Licensed Orthodontic / Dental Professionals</td>
<td>Licensed Orthodontic / Dental Professionals</td>
</tr>
<tr>
<td><strong>Device Description</strong></td>
<td>Radiance Plus is a single-use monocrystalline</td>
<td>Vanish is a single-use monocrystalline</td>
<td>Inspire ICE is a single-use monocrystalline</td>
</tr>
<tr>
<td>Element</td>
<td>Radiance Plus (Predicate Device)</td>
<td>Vanish (Predicate Reference)</td>
<td>Inspire ICE (Proposed Device)</td>
</tr>
<tr>
<td>-------------------------</td>
<td>----------------------------------</td>
<td>------------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td></td>
<td>sapphire orthodontic twin bracket.</td>
<td>sapphire orthodontic twin bracket.</td>
<td>sapphire orthodontic twin bracket.</td>
</tr>
<tr>
<td><strong>Indications for Use</strong></td>
<td>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.</td>
<td>Orthodontic bracket is intended for use by orthodontists to assist in restoring the natural occlusion of teeth.</td>
<td>Intended for use during orthodontic treatment of malocclusions. A malocclusion is the imperfect positioning of the teeth when the jaws are closed.</td>
</tr>
<tr>
<td><strong>Common Name</strong></td>
<td>Orthodontic Ceramic Bracket</td>
<td>Orthodontic Metal Bracket</td>
<td>Orthodontic Ceramic Bracket</td>
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<tr>
<td></td>
<td>Bracket, Ceramic, Dental</td>
<td>Bracket, Metal, Orthodontic</td>
<td>Bracket, Ceramic, Dental</td>
</tr>
<tr>
<td><strong>Classification Name</strong></td>
<td>II</td>
<td>I</td>
<td>II</td>
</tr>
<tr>
<td><strong>Product Code</strong></td>
<td>NJM</td>
<td>EJF</td>
<td>NJM</td>
</tr>
<tr>
<td><strong>Material</strong></td>
<td>Alumina (Al₂O₃)</td>
<td>Alumina (Al₂O₃)</td>
<td>Alumina (Al₂O₃)</td>
</tr>
<tr>
<td><strong>Clarity</strong></td>
<td>Transparent</td>
<td>Transparent</td>
<td>Transparent</td>
</tr>
<tr>
<td><strong>Bracket Design</strong></td>
<td>1-Piece Base and Bracket Construction</td>
<td>1-Piece Base and Bracket Construction</td>
<td>1-Piece Base and Bracket Construction</td>
</tr>
<tr>
<td><strong>Ligation</strong></td>
<td>Non Self-Ligating</td>
<td>Non Self-Ligating</td>
<td>Non Self-Ligating</td>
</tr>
<tr>
<td><strong>Manufacturing Method</strong></td>
<td>Grinding</td>
<td>Grinding</td>
<td>Grinding</td>
</tr>
<tr>
<td><strong>Hooks</strong></td>
<td>Machined Hooks</td>
<td>Machined Hooks</td>
<td>Machined Hooks</td>
</tr>
<tr>
<td><strong>In/Out</strong></td>
<td>Unknown</td>
<td>.035” - .059”</td>
<td>.035” - .050”</td>
</tr>
<tr>
<td><strong>Torque</strong></td>
<td>+17° thru -22°</td>
<td>+17° thru -22°</td>
<td>+17° thru -22°</td>
</tr>
<tr>
<td><strong>Angulation</strong></td>
<td>Up to +10°</td>
<td>Up to +13°</td>
<td>Up to +13°</td>
</tr>
<tr>
<td><strong>Rotation</strong></td>
<td>Up to 4°</td>
<td>Up to 4°</td>
<td>Up to 4°</td>
</tr>
<tr>
<td>Element</td>
<td>Radiance Plus (Predicate Device)</td>
<td>Vanish (Predicate Reference)</td>
<td>Inspire ICE (Proposed Device)</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------</td>
<td>------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Bracket Identification and Placement</strong></td>
<td>Color Coded Visual Placement Aids (VPAs)</td>
<td>Water-Soluble Face Paint™ Identification System</td>
<td>Water-Soluble Face Paint™ Identification System</td>
</tr>
<tr>
<td></td>
<td>Colored dot to indicate Upper/Lower, Left/Right</td>
<td>Colored dot to indicate Upper/Lower, Left/Right</td>
<td>Colored dot to indicate Upper/Lower, Left/Right</td>
</tr>
<tr>
<td><strong>Material Composition for Bracket Identification and Placement</strong></td>
<td>Unknown</td>
<td>Supplier’s proprietary Red, Purple, Green, Yellow, Blue, Orange or Black water-soluble temporary ink/colorant*.</td>
<td>Supplier’s proprietary Red, Purple, Green, Yellow, Blue, Orange or Black water-soluble temporary ink/colorant*.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>*Per an independent accredited medical research service company, the finished device is considered to have met biological evaluation and risk assessment requirements.</td>
<td>*Per an independent accredited medical research service company, the finished device is considered to have met biological evaluation and risk assessment requirements.</td>
</tr>
<tr>
<td><strong>Bracket Base</strong></td>
<td>Quad Matte™ base that is intended to provide variable bond strength across different locations along the base</td>
<td>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</td>
<td>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</td>
</tr>
<tr>
<td><strong>Single Use</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Non-Sterile Packaging</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Debonding Hand Instrument Accessory</strong></td>
<td>Radiance Plus Debonding Pliers (REF: 001-343E) or Omega Ceramic Bracket Debonding Pliers (Sushi pliers REF: 001-301E)</td>
<td>ICE Debonding Plier (REF: 866-4020)</td>
<td>ICE Debonding Plier (REF: 866-4020)</td>
</tr>
</tbody>
</table>
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).