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**ORMCO CORPORATION ANNOUNCES FDA 510(K) CLEARANCE FOR
INSIGNIA™ 3-D ORTHODONTIC SOFTWARE AND CUSTOMIZED APPLIANCES**

*Technology Helps Doctors Differentiate Their Practices with Multiple Treatment Options Ranging from
Aligners to Aesthetic Fixed Appliances*

ORANGE, Calif. (Aug. 15, 2012)—[Ormco Corporation](#), a leading manufacturer and provider of advanced orthodontic technology and services, today announced it received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for [Insignia™](#) Advanced Smile Design, a combination of 3-D treatment software and customized appliances to help clinicians increase treatment efficiency and deliver patient results with a higher degree of precision.

The 510(k) clearance paves the way for the only system of its kind with an expansive menu of treatment options ranging from aligners to fixed appliances such as Damon Clear™, which already has strong appeal among teens and adults. Unique to Insignia, clinicians have the option to choose traditional twins, self-ligating brackets or aligners that are customized to the individual patient, achieving the results of the doctor-approved treatment plan with incredible efficiency. Compatible appliances include [Insignia™ Clearguide™ Express](#) aligners, Damon® Q™, Damon Clear, Titanium Orthos™ and Inspire ICE™.

“Insignia is the result of decades of research and innovation and delivers on our mission to provide orthodontists with the widest array of high-tech treatment options so that they can provide the best possible results for each individual patient in the most efficient way,” said Vicente Reynal, president of Ormco. “Insignia is backed by Ormco Digital Solutions Specialists, a well-educated product support team that ensures all users are properly trained on software functions and treatment options. Insignia will also help Treatment Coordinators convert consults into patients, since it can showcase what an individual’s final smile will look like before treatment begins.”

The only orthodontic software and appliance system that delivers a complete customized solution from initial smile design to fabrication of patient-specific aligners or brackets and wires, Insignia helps reduce mid-treatment adjustments and overall treatment time, since appliances are specific to each patient’s unique dental anatomy.

Insignia uses a high-resolution scan of a PVS impression to create a precise 3-D virtual model of the patient’s dental anatomy. Utilizing more than 40,000 data points per tooth, unique algorithms in the software define, coordinate and design the patient’s arches into the best possible occlusion. The doctor

(more)

then uses this initial occlusion to apply a more finite level of design, taking into consideration facial features and treatment preferences to create the perfect smile, unique to each person treated.

Fixed appliances are delivered in Precision Placement Guides—or jigs—for easy, precise bracket placement by chairside assistants, helping clinicians achieve the final smile and occlusion outcome in the most efficient way possible.

Insignia users also will benefit from greater practice differentiation and growth as a result of Ormco's aggressive Insignia consumer education campaign, which involves a number of search engine marketing and PR programs to drive prospective patients to www.insigniasmile.com where they will be able to locate an Insignia doctor. A full range of turnkey in-office consultation materials ranging from lobby videos to TC presentations also are available exclusively to Insignia users.

Media interested in speaking with an Ormco spokesperson should contact Robin Dwyer at 619-234-0345 or ormco@formulapr.com. Connect on Facebook at www.facebook.com/InsigniaSmile, or Twitter at [@Ormco](https://twitter.com/Ormco).

About Ormco

Ormco is dedicated to manufacturing innovative products that improve the clinician's opportunity to achieve excellent results in the least amount of time, in the fewest number of appointments, and with the greatest patient comfort. Distinguished products range from legacy twins Titanium Orthos™ and Mini-Twin™ to self-ligation with the Damon® System and new active Prodigy™ SL as well as Insignia™ Clearguide™ Express, which puts aligner design control in the doctors' hands. From personalized service to worldwide continuing education programs and marketing support, Ormco is committed to helping orthodontists achieve their clinical and practice management objectives. For more information, visit the Ormco website.

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