

17<sup>th</sup> January 2024

Los Angeles Area Chamber of Commerce  
350 S. Bixel Street  
Los Angeles, CA 90017

Dear LAACC,

Bay Materials LLC has been in business here in the Silicon Valley area since 2001 and in our present Fremont location since 2015. Our firm develops and manufactures specialty plastic materials for a wide variety of applications. We developed a thermoplastic polyurethane sheet material for use in thermoforming dental/orthodontic appliances in 2011 and we manufacture and market this material under the brand name "ZenduraDental" ([www.zenduradental.com](http://www.zenduradental.com)).

Today we manufacture orthodontic materials under the following brand names:

- Zendura®
- Zendura® A
- Zendura FLX®
- Zendura® TRAK

Bay Materials produces these thermoformable sheet materials exclusively in our production facility in Fremont, California and ships them to clinicians, dental labs and orthodontic appliance manufacturing companies worldwide. In the USA and many other countries, these plastic sheet materials are considered raw materials or production components and are not regulated as medical devices.

Thank you!

Sincerely,



Dr. Mayuri Kerr  
DDS, MS  
Director, Clinical & Regulatory Affairs

**BayMaterials**  
A Straumann Group Brand

**Bay Materials, LLC**  
48450 Lakeview Blvd  
Fremont, CA 94538 USA

