



This is to attest that:

**OrthoAccel Technologies, Inc.
6575 West Loop South
Suite 200
Bellaire, TX 77401**

Has been granted U.S. Food and Drug Administration (FDA) 510(k) clearance of the following medical device:

510(k) Number: K110661
TM Trade/Device Name: AcceleDent® System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: OYH

OrthoAccel Technologies may market the aforementioned device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (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.

Indication for Use:

AcceleDent® is an orthodontic accessory intended for use during orthodontic treatment. It is used in conjunction with orthodontic appliances such as braces and helps facilitate minor anterior tooth movement.

