



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

|                                |  |   |
|--------------------------------|--|---|
| <b>Summary for ARTG Entry:</b> | 370901   | American Orthodontics Aust/NZ Pty Ltd - Orthodontic separator |
| <b>ARTG entry for</b>          | Medical Device Included Class IIa                                  |   |
| <b>Sponsor</b>                 | American Orthodontics Aust/NZ Pty Ltd                              |   |
| <b>Postal Address</b>          | Suite 101/63 Stead Street, SOUTH MELBOURNE, VIC, 3205<br>Australia |   |
| <b>ARTG Start Date</b>         | 12/07/2021   |   |
| <b>Product Category</b>        | Medical Device Class IIa   |   |
| <b>Status</b>                  | Active   |   |
| <b>Approval Area</b>           | Medical Devices  |   |

**Conditions**

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.  
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

**Manufacturers**

| Name                       | Address  |
|----------------------------|--|
| American Orthodontics Corp | 3524 Washington Avenue<br>Sheboygan, WI, 53081<br>United States Of America |

**Products**

| 1 . Orthodontic separator |   |                |  |
|---------------------------|---|----------------|--|
| Product Type              |   | Effective Date |  |
| Single Device Product     |   | 12/07/2021     |  |
| <b>GMDN</b>               | 63708 Orthodontic separator   |                |  |
| <b>Intended Purpose</b>   | A non-sterile orthodontic device intended to be placed between adjacent teeth to slowly move them apart to help achieve improved positioning and/or appearance of the teeth. It is typically in the form of a loop or ring and is made of synthetic polymer materials. This is a single-patient device intended to be used for the duration of the treatment (single-use) before being discarded. |                |  |

**Specific Conditions**  
No Specific Conditions included on Record

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