FDA 510(k) Premarket Notification

**CLEARED**

# K893483 BONDABLE RETAINER AND SPACE MAINTAINER

Jul 14, 1989
71 days to decision

K893483 · Product code: **EJF** · Dental
Source: https://www.510kdatabase.net/k893483/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Bracket, Metal, Orthodontic (EJF) |
| Date received | May 4, 1989 |
| Decision date | Jul 14, 1989 |
| Days to decision | 71 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **American Orthodontics** |
| Location | Sheboygan, WI, US |
| Contact | PAUL RIDDLE |
| 510(k) history | 45 submissions · 45 cleared · 1989-2026 |

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k893483/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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