

K261129 OrthoFit

Jul 2, 2026
87 days to decision

K261129 · Product code: **DYH** · Dental
Source: <https://www.510kdatabase.net/k261129/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adhesive, Bracket And Tooth Conditioner, Resin (DYH)
Date received	Apr 6, 2026
Decision date	Jul 2, 2026
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spident Co., Ltd.
Location	Incheon, KR
Contact	Choi Eunok
510(k) history	18 submissions · 18 cleared · 2009-2026