

K260268 OrthoEasy PalMay 19, 2026
111 days to decisionK260268 · Product code: **OAT** · Dental
Source: <https://www.510kdatabase.net/k260268/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Orthodontic (OAT)
Date received	Jan 28, 2026
Decision date	May 19, 2026
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	OrthoEasy Pal Long Neck

APPLICANT

Company	Bernhard Förster GmbH (Bernhard Foerster Ltd.)
Location	Pforzheim, DE
Contact	Stefan Förster
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Compliance 4 Devices, Ltd.
Contact	Juan Tezak

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k260268/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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