

K231913 T-FITFeb 8, 2024
224 days to decisionK231913 · Product code: **OAT** · Dental
Source: <https://www.510kdatabase.net/k231913/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Orthodontic (OAT)
Date received	Jun 29, 2023
Decision date	Feb 8, 2024
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Techwin Co., Ltd.
Location	Siheung-Si, KR
Contact	Min-jae Jo
510(k) history	2 submissions · 2 cleared · 2024-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231913/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026