

K233419 GBR SystemJan 3, 2025
451 days to decisionK233419 · Product code: **DZL** · Dental
Source: <https://www.510kdatabase.net/k233419/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Intraosseous (DZL)
Date received	Oct 10, 2023
Decision date	Jan 3, 2025
Days to decision	451 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Proimtech Saglik Urunleri Anonim Sirketi
Location	Istanbul, TR
Contact	Hakan Cevik
510(k) history	3 submissions · 3 cleared · 2024-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233419/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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