

**K243190 USTOMED Bone Fixation/Bone Augmentation Systems
- PIN**Jun 27, 2025
270 days to decisionK243190 · Product code: **DZL** · Dental
Source: <https://www.510kdatabase.net/k243190/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Intraosseous (DZL)
Date received	Sep 30, 2024
Decision date	Jun 27, 2025
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ustomed Instrumente Ulrich Storz GmbH & Co. KG
Location	Tuttlingen, DE
Contact	Alexander Schwoy
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Business Support International
Contact	Angelika Scherp

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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