

K253130 Dione PEEK Screw SystemMay 27, 2026
244 days to decisionK253130 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k253130/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 25, 2025
Decision date	May 27, 2026
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	ZheJiang Decans Medical Devices Co., Ltd.
Location	Jiaxing, CN
Contact	Haifeng Liu
510(k) history	9 submissions · 9 cleared · 2024-2026

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