FDA 510(k) Premarket Notification

K241073 DZ-Tabone Intervertebral Body Fusion Device

CLEARED

Dec 6, 2024
231 days to decision

K241073 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k241073/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Apr 19, 2024
Decision date	Dec 6, 2024
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Dazhou Medical Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Jingzhou Yang
510(k) history	2 submissions · 2 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	**Cosmos Biomed Consulting**
Contact	Ray Chang

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