FDA 510(k) Premarket Notification

K232115 TDM Large Bone Plate and Screw System

CLEARED

Apr 5, 2024
266 days to decision

K232115 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k232115/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jul 14, 2023
Decision date	Apr 5, 2024
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tdm Co., Ltd.**
Location	Gwangju, KR
Contact	Dave Kim
510(k) history	11 submissions · 11 cleared · 2018-2024

REGULATORY CONSULTANT

Consulting firm	**Mtech Group, LLC**
Contact	Dave Kim

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