FDA 510(k) Premarket Notification

K230394 EUROSCREW NG

CLEARED

May 12, 2023
87 days to decision

K230394 · Product code: **MAI** · Orthopedic
Source: https://www.510kdatabase.net/k230394/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Feb 14, 2023
Decision date	May 12, 2023
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	EUROSCREW TCP NG

APPLICANT

Company	**Teknimed**
Location	L'Union, FR
Contact	Fabian Marcq
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**RQMIS, Inc.**
Contact	Barry E Sands

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