

K251063 TekBrace Solo Soft Tissue Reinforcement Device

May 30, 2025
56 days to decision

K251063 · Product code: **QUW** · Orthopedic
Source: <https://www.510kdatabase.net/k251063/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Non-resorbable, Orthopedics, Reinforcement Of Ligament (QUW)
Date received	Apr 4, 2025
Decision date	May 30, 2025
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Theramicro
Location	Cordova, TN, US
Contact	Christine Scifert
510(k) history	2 submissions · 2 cleared · 2025-2026
