FDA 510(k) Premarket Notification

CLEARED

K242237 Jewel Soft Tissue Reinforcement Device (102-6005)

Jul 15, 2025
350 days to decision

K242237 · Product code: **QUW** · Orthopedic
Source: https://www.510kdatabase.net/k242237/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Non-resorbable, Orthopedics, Reinforcement Of Ligament (QUW)
Date received	Jul 30, 2024
Decision date	Jul 15, 2025
Days to decision	350 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Xiros Limited**
Location	Yeadon, GB
Contact	Grannells Janet
510(k) history	1 submissions · 1 cleared · 2025-2025