FDA 510(k) Premarket Notification

CLEARED

K222220 SpinMedix Absorbable Fibrous Membrane

Jul 6, 2023
346 days to decision

K222220 · Product code: **OWW** · Orthopedic
Source: https://www.510kdatabase.net/k222220/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Absorbable, Orthopaedics, Reinforcement Of Tendon (OWW)
Date received	Jul 25, 2022
Decision date	Jul 6, 2023
Days to decision	346 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Celestray Biotech Company, LLC.,**
Location	Bethesda, MD, US
Contact	Charles C Han
510(k) history	2 submissions · 2 cleared · 2023-2024