

K261770 Suture Button Repair System

Jul 29, 2026
61 days to decision

K261770 · Product code: MBI · Orthopedic
Source: <https://www.510kdatabase.net/k261770/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	May 29, 2026
Decision date	Jul 29, 2026
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Skeletal Dynamics, Inc.
Location	Miami, FL, US
Contact	Alexandra Rodriguez
510(k) history	21 submissions · 21 cleared · 2020-2026