

K240835 Suture Button Repair SystemJul 19, 2024
115 days to decisionK240835 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k240835/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Mar 26, 2024
Decision date	Jul 19, 2024
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Skeletal Dynamics, Inc.
Location	Miami, FL, US
Contact	Alexandra Rodriguez Rojas
510(k) history	20 submissions · 20 cleared · 2020-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240835/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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