FDA 510(k) Premarket Notification

CLEARED

K251709 MedCAD® AccuStride™ System

Nov 4, 2025
154 days to decision

K251709 · Product code: **PBF** · Orthopedic
Source: https://www.510kdatabase.net/k251709/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopaedic Surgical Planning And Instrument Guides (PBF)
Date received	Jun 3, 2025
Decision date	Nov 4, 2025
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medcad**
Location	Dallas, TX, US
Contact	Brian Buss
510(k) history	9 submissions · 9 cleared · 2020-2026

REGULATORY CONSULTANT

Consulting firm	**Secure BioMed Evaluations**
Contact	Justin Gracyalny

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov