

K250435 Dexter L6 SystemMay 27, 2025
102 days to decisionK250435 · Product code: **SDD** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250435/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electromechanical Surgical System Wherein The Surgeon Annd The User Interface Can Be In The Sterile Field (SDD)
Date received	Feb 14, 2025
Decision date	May 27, 2025
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Distalmotion SA
Location	Epalinges, CH
Contact	Larry Carrier
510(k) history	3 submissions · 2 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Lina Kontos

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250435/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026