

K251197 Dexter L6 SystemSep 30, 2025
166 days to decisionK251197 · Product code: **SDD** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251197/>**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	Apr 17, 2025
Decision date	Sep 30, 2025
Days to decision	166 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

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