

K241790 XCELLARISPRO TWIST microneedling deviceMar 6, 2025
258 days to decisionK241790 · Product code: **QAI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k241790/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Microneedle Device (QAI)
Date received	Jun 21, 2024
Decision date	Mar 6, 2025
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dermaroller GmbH
Location	Wolfenbuettel, DE
Contact	Anna Lena Kaufholz
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Buchanan
Contact	Barbara A. Binzak Blumenfeld

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/k241790/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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