

K200659 Dermalux Tri-Wave MDMay 9, 2020
58 days to decisionK200659 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k200659/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 12, 2020
Decision date	May 9, 2020
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aesthetic Technology, Ltd.
Location	Warrington, GB
Contact	Dale Needham
510(k) history	4 submissions · 4 cleared · 2020-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200659/> 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 26, 2026