

K253251 Leaseir MHR Xcell (console) (MHR-100b)May 4, 2026
217 days to decisionK253251 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253251/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 29, 2025
Decision date	May 4, 2026
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Handpiece: Dual (810-b and Blend-b); Handpiece: Quad (810-b and Blend-b)

APPLICANT

Company	Leaseir Technologies, Slu
Location	Gijón, ES
Contact	Sergio Camacho Santiago
510(k) history	2 submissions · 2 cleared · 2022-2026

REGULATORY CONSULTANT

Consulting firm	Paladin Medical, Inc.
Contact	Sergio C Santiago

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253251/> 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 June 28, 2026