FDA 510(k) Premarket Notification

K214049 Leaseir MHR Xcell

CLEARED

Jun 2, 2022
157 days to decision

K214049 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k214049/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 27, 2021
Decision date	Jun 2, 2022
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Leaseir Technologies, Slu**
Location	Gij?n, ES
Contact	Pablo Boto
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Freyr Global Regulatory Solutions and Services**
Contact	Vardhini Kirthivas

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