

K213267 Dynamis Pro FamilySep 8, 2022
343 days to decisionK213267 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213267/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 30, 2021
Decision date	Sep 8, 2022
Days to decision	343 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fotona D.O.O.
Location	Ljubljana, SI
Contact	Marko Berdajs
510(k) history	16 submissions · 16 cleared · 2017-2025

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