

K210183 Waterlase iPLusApr 21, 2022
451 days to decisionK210183 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k210183/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 25, 2021
Decision date	Apr 21, 2022
Days to decision	451 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biolase, Inc.
Location	Irvine, CA, US
Contact	Katy Nennig
510(k) history	10 submissions · 10 cleared · 2014-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210183/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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