

K190319 Waterlase Laser System FamilyOct 10, 2019
239 days to decisionK190319 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k190319/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 13, 2019
Decision date	Oct 10, 2019
Days to decision	239 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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