

K163128 Epic ProJan 11, 2017
64 days to decisionK163128 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k163128/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 8, 2016
Decision date	Jan 11, 2017
Days to decision	64 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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