

K193486 Epic 980Mar 16, 2020
90 days to decisionK193486 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k193486/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 17, 2019
Decision date	Mar 16, 2020
Days to decision	90 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193486/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026