

K212082 PicoreOct 6, 2021
96 days to decisionK212082 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212082/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 2, 2021
Decision date	Oct 6, 2021
Days to decision	96 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Med USA, Inc.
Location	Paterson, NJ, US
Contact	Young Chi
510(k) history	10 submissions · 10 cleared · 2008-2022

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