

K153124 DuraLaze™ HoLEP Laser FiberJul 26, 2016
271 days to decisionK153124 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k153124/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 29, 2015
Decision date	Jul 26, 2016
Days to decision	271 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medkey, LLC
Location	Bloomington, IN, US
Contact	Jeff Zerfas
510(k) history	1 submissions · 1 cleared · 2016-2016

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