

K161632 FAMILY OF SQUARE EPIL (Alex, Alex2, Nd:Yag, Alex+Nd:Yag)

Dec 8, 2016
178 days to decision

K161632 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k161632/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 13, 2016
Decision date	Dec 8, 2016
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bios S.R.L.
Location	Silver Spring, MD, US
Contact	Riccardo Pisati
510(k) history	14 submissions · 14 cleared · 2005-2024

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k161632/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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