FDA 510(k) Premarket Notification

K172771 Epic Pro 940

CLEARED

Nov 29, 2017
76 days to decision

K172771 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k172771/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 14, 2017
Decision date	Nov 29, 2017
Days to decision	76 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