FDA 510(k) Premarket Notification

CLEARED

K142638 ProFlex Laser Fibers (ProFlex 200) and ProFlex Laser Fibers (PRoFlex 273)

Dec 19, 2014
93 days to decision

K142638 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k142638/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 17, 2014
Decision date	Dec 19, 2014
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Innovaquartz, LLC**
Location	Phoenix, AZ, US
Contact	Stephen Griffin
510(k) history	4 submissions · 4 cleared · 2014-2024

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k142638/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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