FDA 510(k) Premarket Notification

K152611 V20 system

CLEARED

Feb 19, 2016
158 days to decision

K152611 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k152611/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 14, 2015
Decision date	Feb 19, 2016
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Viora , Ltd.**
Location	Jersey City, NJ, US
Contact	OMRI KESLER
510(k) history	11 submissions · 11 cleared · 2009-2020