FDA 510(k) Premarket Notification

K153229 Superbium

CLEARED

Apr 12, 2016
158 days to decision

K153229 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k153229/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 6, 2015
Decision date	Apr 12, 2016
Days to decision	158 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