FDA 510(k) Premarket Notification

K191321 Primelase Excellence

CLEARED

Aug 2, 2019
79 days to decision

K191321 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k191321/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 15, 2019
Decision date	Aug 2, 2019
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**High Technology Products S.L.U**
Location	Barcelona, ES
Contact	Sergi Lozano
510(k) history	3 submissions · 3 cleared · 2019-2020

REGULATORY CONSULTANT

Consulting firm	**Freyr Global Regulatory Solutions and Services**
Contact	Vardhini Kirthivas

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov