FDA 510(k) Premarket Notification

K200693 K2 MOBILE

CLEARED

Nov 19, 2020
248 days to decision

K200693 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k200693/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 16, 2020
Decision date	Nov 19, 2020
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hulaser, Inc.**
Location	Seoul, KR
Contact	InBae Park
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**KMC, Inc.**
Contact	DongHa Lee

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