FDA 510(k) Premarket Notification

K192569 Diode Laser Therapy System

CLEARED

Dec 13, 2019
86 days to decision

K192569 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k192569/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 18, 2019
Decision date	Dec 13, 2019
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**San HE Lefis Electronics Co., Ltd.**
Location	Yanjiao Development Zone, Sanhe County,, CN
Contact	Ning Li
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Beijing Believe-Med Technology Service Co., Ltd.**
Contact	Ray Wang

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