FDA 510(k) Premarket Notification

K191571 UV Radiation Treatment System

CLEARED

Feb 6, 2020
237 days to decision

K191571 · Product code: **FTC** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k191571/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Ultraviolet, Dermatological (FTC)
Date received	Jun 14, 2019
Decision date	Feb 6, 2020
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Xuzhou Yongkang Electronic Science Technology Co., Ltd.**
Location	Xuzhou, CN
Contact	Kai Li
510(k) history	6 submissions · 6 cleared · 2017-2026

REGULATORY CONSULTANT

Consulting firm	**Shanghai Truthful Information Technology Co., Ltd.**
Contact	Boyle Wang

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