FDA 510(k) Premarket Notification

K200971 308nm Excimer System

CLEARED

Dec 15, 2020
246 days to decision

K200971 · Product code: **FTC** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k200971/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Ultraviolet, Dermatological (FTC)
Date received	Apr 13, 2020
Decision date	Dec 15, 2020
Days to decision	246 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Xuzhou Kernel Medical Equipment Co., Ltd.**
Location	Shanghai, CN
Contact	Jing Wang
510(k) history	8 submissions · 8 cleared · 2014-2025