FDA 510(k) Premarket Notification

K172273 308nm Excimer System

CLEARED

Jul 30, 2018
367 days to decision

K172273 · Product code: **FTC** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k172273/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Ultraviolet, Dermatological (FTC)
Date received	Jul 28, 2017
Decision date	Jul 30, 2018
Days to decision	367 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Chongqing Peninsula Medical Technology Co., Ltd.**
Location	Jiulongpo District, CN
Contact	Zhang Sudi
510(k) history	4 submissions · 4 cleared · 2018-2020

REGULATORY CONSULTANT

Consulting firm	**Guangzhou GLOMED Biological Technology Co., Ltd.**
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Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov