FDA 510(k) Premarket Notification

CLEARED

K222432 IPL Hair Removal Device, Model(s): KCA423, KCA437, KCA439

Oct 11, 2022
60 days to decision

K222432 · Product code: **OHT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222432/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over-the-counter Hair Removal (OHT)
Date received	Aug 12, 2022
Decision date	Oct 11, 2022
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hunan Guangye Biotechnology Co., Ltd.**
Location	Changsha City, CN
Contact	Eileen Li
510(k) history	2 submissions · 2 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
Contact	Tracy Che

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