FDA 510(k) Premarket Notification

K220248 Home use hair removal device

CLEARED

Jul 1, 2022
151 days to decision

K220248 · Product code: **OHT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220248/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over-the-counter Hair Removal (OHT)
Date received	Jan 31, 2022
Decision date	Jul 1, 2022
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Mareal Tech Co., Ltd.**
Location	Shenzhen, CN
Contact	Liu Libin
510(k) history	2 submissions · 2 cleared · 2018-2022

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
Contact	Rain Yip

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