FDA 510(k) Premarket Notification

K220322 Pollogen STOP U Model UXV Device

CLEARED

May 4, 2023
455 days to decision

K220322 · Product code: **PAY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220322/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Radiofrequency Coagulation Device For Wrinkle Reduction (PAY)
Date received	Feb 3, 2022
Decision date	May 4, 2023
Days to decision	455 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pollogen, Ltd.**
Location	Binyamina, IL
Contact	Elissa Burg
510(k) history	18 submissions · 18 cleared · 2011-2025

REGULATORY CONSULTANT

Consulting firm	**BioVision , Ltd.**
Contact	Elissa Burg

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