

**K203665 STOP U Model UXV Device**Feb 25, 2021  
71 days to decisionK203665 · Product code: **PAY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k203665/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Over-the-counter Radiofrequency Coagulation Device For Wrinkle Reduction (PAY)
Date received	Dec 16, 2020
Decision date	Feb 25, 2021
Days to decision	71 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pollogen, Ltd.</b>
Location	Binyamina, IL
Contact	Ayala Kamil
510(k) history	18 submissions · 18 cleared · 2011-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>BioVision , Ltd.</b>
Contact	Elissa Burg

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203665/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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