

**K182774 STOP U (Packed Black USA), STOP U (Packed White USA)**Jun 19, 2019  
261 days to decisionK182774 · Product code: **PAY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k182774/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Radiofrequency Coagulation Device For Wrinkle Reduction (PAY)
Date received	Oct 1, 2018
Decision date	Jun 19, 2019
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182774/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026