

K202055 Looper (Model: ZX-579S)Apr 16, 2021
266 days to decisionK202055 · Product code: **OLP** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k202055/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Powered Light Based Laser For Acne (OLP)
Date received	Jul 24, 2020
Decision date	Apr 16, 2021
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Heat IN A Click, LLC
Location	Dania, FL, US
Contact	Guy Levi
510(k) history	6 submissions · 6 cleared · 2015-2025

REGULATORY CONSULTANT

Consulting firm	Guangzhou GLOMED Biological Technology Co., Ltd.
Contact	Cassie Lee

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

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