

K200616 E>EyeCJun 11, 2020
94 days to decisionK200616 · Product code: **ONF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k200616/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Mar 9, 2020
Decision date	Jun 11, 2020
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	E-Swin
Location	Houdan, FR
Contact	Emeric OBIN
510(k) history	1 submissions · 1 cleared · 2020-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200616/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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