

K191086 ExciplexDec 11, 2019
231 days to decisionK191086 · Product code: **FTC** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k191086/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Ultraviolet, Dermatological (FTC)
Date received	Apr 24, 2019
Decision date	Dec 11, 2019
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Clarteis
Location	Valbonne, FR
Contact	Laurent Meilhac
510(k) history	2 submissions · 2 cleared · 2017-2019

REGULATORY CONSULTANT

Consulting firm	Acknowledge Regulatory Strategies, LLC
Contact	Lucie Dalet

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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