

K212492 Frax 1940 for Nordlys and Frax ProDec 20, 2021
133 days to decisionK212492 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k212492/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 9, 2021
Decision date	Dec 20, 2021
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Candela Corporation
Location	Wayland, MA, US
Contact	Rina Ordonez
510(k) history	8 submissions · 8 cleared · 2015-2024

CLINICAL EVIDENCE - NCT04203745**Nonablative Fractional Diode Laser for Treatment of Skin Resurfacing and Pigmented Lesions**

Status	Completed
Enrollment	26 patients (actual)
Study sites	1 site
Condition studied	Skin Texture; Pigmented Lesions
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Aug 5, 2021
Sponsor	Candela Corporation (Industry)

Primary outcome**Pigmented Lesion Improvement by Blinded Evaluation**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04203745510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212492/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).
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