FDA 510(k) Premarket Notification

K202848 S2 Pigment Removal System

CLEARED

Dec 14, 2021
445 days to decision

K202848 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k202848/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 25, 2020
Decision date	Dec 14, 2021
Days to decision	445 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lightsense Technologies, Ltd.**
Location	London, GB
Contact	Deganit Barak
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	John Smith

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

CLINICAL EVIDENCE - NCT03866304

Performance Evaluation of Tattoo Removal

Status	Unknown - *No results published to ClinicalTrials.gov*
Enrollment	60 patients (estimated)
Study sites	1 site
Condition studied	Tattoo Removal
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Aug 31, 2019
Sponsor	LigthSense Israel Ltd (Industry)

Primary outcome

Tattoo clearing

Secondary outcome

Degree of tattoo clearing as assessed by PGA

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03866304