FDA 510(k) Premarket Notification

K202955 Contour Light CL-100

CLEARED

May 19, 2021
231 days to decision

K202955 · Product code: **OLI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k202955/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fat Reducing Low Level Laser (OLI)
Date received	Sep 30, 2020
Decision date	May 19, 2021
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Contour Research, LLC**
Location	Reno, NV, US
Contact	Doug Dreier
510(k) history	2 submissions · 2 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	**Bentley Biomedical Consulting, LLC**
Contact	Shepard G. Bentley

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

CLINICAL EVIDENCE - NCT04451824

Examination of Circumferential Reduction

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	118 patients (actual)
Study sites	3 sites
Condition studied	Overweight or Obesity
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Dec 31, 2018
Sponsor	Contour Research (Industry)

Primary outcome

Examination of Circumferential Reduction - Primary Objective

Secondary outcome

Examination of Circumferential Reduction - Secondary Objective

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04451824

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k202955/ Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).
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