FDA 510(k) Premarket Notification

K212399 Aveli

CLEARED

Oct 22, 2021
81 days to decision

K212399 · Product code: **OUP** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k212399/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Surgical Instrument For Improvement In The Appearance Of Cellulite (OUP)
Date received	Aug 2, 2021
Decision date	Oct 22, 2021
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nc8, Inc.**
Location	Mountain View, CA, US
Contact	Mellissa Viotti
510(k) history	1 submissions · 1 cleared · 2021-2021

CLINICAL EVIDENCE - NCT04743635

CONtrolled Focal Fibrous Band Release Method Study

Status	Completed
Enrollment	74 patients (actual)
Study sites	9 sites
Condition studied	Cellulite
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Mar 4, 2022
Sponsor	Revelle Aesthetics, Inc (Industry)

Primary outcome

The Mean Change From Baseline to 3 Months in Cellulite Severity Scale (CSS) Score for Participants

Secondary outcome

Percentage of Participants With Improvement as Assessed Using Global Aesthetic Improvement Scale (GAIS) at 3 Months

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04743635