

K221336 AvéliAug 5, 2022
88 days to decisionK221336 · Product code: **OUP** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k221336/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Surgical Instrument For Improvement In The Appearance Of Cellulite (OUP) |
| Date received | May 9, 2022 |
| Decision date | Aug 5, 2022 |
| Days to decision | 88 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Revelle Aesthetics, Inc. |
| Location | Mountain View, CA, US |
| Contact | Melissa Viotti |
| 510(k) history | 2 submissions · 2 cleared · 2022-2023 |

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