

K250402 AVAVA™ Skin Treatment SystemApr 14, 2025
61 days to decisionK250402 · Product code: **ONG** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k250402/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument With Microbeamfractional Output (ONG)
Date received	Feb 12, 2025
Decision date	Apr 14, 2025
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Avava, Inc.
Location	Waltham, MA, US
Contact	Richard Bankowski
510(k) history	6 submissions · 6 cleared · 2021-2025

CLINICAL EVIDENCE - NCT05597267**The MIRIA Acne Scar Study**

Status	Active not recruiting - <i>No results published to ClinicalTrials.gov</i>
Enrollment	75 patients (estimated)
Study sites	3 sites
Condition studied	Acne Scars - Mixed Atrophic and Hypertrophic
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Feb 28, 2025
Sponsor	AVAVA, Inc. (Industry)

Primary outcome

ECCA (échelle d'évaluation clinique des cicatrices d'acné) Grading

Secondary outcome

Blinded Evaluation of Treatment Imaging

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05597267