

K181518 Sebacia MicroparticlesSep 6, 2018
90 days to decisionK181518 · Product code: **QCY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k181518/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser Absorbing Particles (QCY)
Date received	Jun 8, 2018
Decision date	Sep 6, 2018
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sebacia, Inc.
Location	Duluth, GA, US
Contact	Todd J. Meyer
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	John J. Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**CLINICAL EVIDENCE - NCT03303170****Non-Significant Risk Study of Sebacia Microparticles in the Treatment of Facial Acne Vulgaris**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	168 patients (actual)
Study sites	11 sites
Condition studied	Acne Vulgaris
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Single blind
Completion date	Apr 10, 2018
Sponsor	Sebacia, Inc. (Industry)

Primary outcome

Change in number of inflammatory acne lesions

Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03303170