

K211681 EONMar 30, 2022
302 days to decisionK211681 · Product code: **PKT** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k211681/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser For Disruption Of Adipocyte Cells For Aesthetic Use (PKT)
Date received	Jun 1, 2021
Decision date	Mar 30, 2022
Days to decision	302 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dominion Aesthetic Technologies, Inc.
Location	Winter Park, FL, US
Contact	Ahmed Mohammed
510(k) history	3 submissions · 3 cleared · 2019-2023

CLINICAL EVIDENCE - NCT04797988

Eon® Flanks Safety Clinical Study Protocol

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	11 patients (actual)
Study sites	1 site
Condition studied	Adipose Tissue
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	May 15, 2021
Sponsor	Dominion Aesthetic Technologies, Inc. (Industry)

Primary outcome

Safety Evaluation eon® treatment of the flanks (Adverse Events)

Secondary outcome**Subject Satisfaction**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04797988
