

K251077 JOULE 1064nm System and Accessories

Dec 19, 2025
255 days to decision

K251077 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k251077/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 8, 2025
Decision date	Dec 19, 2025
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sciton, Inc
Location	Palo Alto, CA, US
Contact	Jay Patel
510(k) history	23 submissions · 23 cleared · 2000-2025

CLINICAL EVIDENCE - NCT04744935

Optical Coherence Tomography Guided Laser Treatment of Basal Cell Carcinoma

Status	Active not recruiting - <i>No results published to ClinicalTrials.gov</i>
Enrollment	40 patients (estimated)
Study sites	1 site
Condition studied	Basal Cell Carcinoma; Superficial Basal Cell Carcinoma; Nodular Basal Cell Carcinoma
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Feb 17, 2027
Sponsor	Christopher Zachary (Other)

Primary outcome

Complete histological clearance of BCC lesion

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04744935