

K201466 Tranberg CLS Laser ApplicatorMar 26, 2021
297 days to decisionK201466 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k201466/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 2, 2020
Decision date	Mar 26, 2021
Days to decision	297 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Clinical Laserthermia Systems, AB
Location	Lund, SE
Contact	Lars-Erik Eriksson
510(k) history	6 submissions · 6 cleared · 2015-2025

REGULATORY CONSULTANT

Consulting firm	Omedtech, LLC
Contact	David Makanani

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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