

**K011769 OPUS 10 (WITH TOOTH WHITENING APPLICATION),
MODEL 2ND**Aug 30, 2001
84 days to decisionK011769 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k011769/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 7, 2001
Decision date	Aug 30, 2001
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Opusdent , Ltd.
Location	Ra'Ananna, IL
Contact	SHOSHANA FRIEDMAN
510(k) history	5 submissions · 5 cleared · 2000-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011769/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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