

**K980389 MEGABEAM REUSABLE FIBER OPTIC HANDPIECE
AND NEEDLES**Jul 29, 1998
177 days to decisionK980389 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k980389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 2, 1998
Decision date	Jul 29, 1998
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ceram Optec, Inc.
Location	Washington, DC, US
Contact	JONATHAN S KAHAN
510(k) history	30 submissions · 30 cleared · 1992-2000

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