

K971912 PROTEGE ER:YAG LASER SYSTEM AND ACCESSORIESNov 3, 1997
206 days to decisionK971912 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k971912/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 11, 1997
Decision date	Nov 3, 1997
Days to decision	206 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Xintec Corporation
Location	Oakland, CA, US
Contact	MARILYN M CHOU
510(k) history	26 submissions · 26 cleared · 1990-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971912/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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