

K000222 UM-L25Apr 19, 2000
86 days to decisionK000222 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k000222/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 24, 2000
Decision date	Apr 19, 2000
Days to decision	86 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Union Medical Engineering Co., Ltd.
Location	Miami, FL, US
Contact	ANNIE VELEZ
510(k) history	2 submissions · 2 cleared · 1999-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k000222/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 3, 2026