

K895239 MODEL IR107 50-WATT CARBON-DIOXIDE SURGICAL LASERNov 16, 1989
87 days to decisionK895239 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k895239/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 21, 1989
Decision date	Nov 16, 1989
Days to decision	87 days
Third-party review	No

APPLICANT

Company	Niic U.S.A., Inc.
Location	Redwood City, CA, US
Contact	MICHAEL MORETTI
510(k) history	16 submissions · 16 cleared · 1988-1990

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k895239/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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