

**K013901 MALLEABLE SURGICAL LIGHTSTIC 180, MODEL 180
(1CM-9CM)**Dec 20, 2001
24 days to decisionK013901 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k013901/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 26, 2001
Decision date	Dec 20, 2001
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardiofocus, Inc.
Location	Norton, MA, US
Contact	JOSEPH CURTIS
510(k) history	5 submissions · 5 cleared · 2000-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013901/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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