FDA 510(k) Premarket Notification

K945126 ECLIPSE 3200

CLEARED

Jan 18, 1995
91 days to decision

K945126 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k945126/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 19, 1994
Decision date	Jan 18, 1995
Days to decision	91 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Cardiogenes**
Location	Palo Alto, CA, US
Contact	DOUGLAS MURPHY-CHUTORIAN
510(k) history	20 submissions · 19 cleared · 1992-1997

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k945126/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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