FDA 510(k) Premarket Notification

K924943 ECLIPSE 3200(TM) HO:YAG LASER FOR PERCU DISKETOMY

CLEARED

May 17, 1993
236 days to decision

K924943 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k924943/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 23, 1992
Decision date	May 17, 1993
Days to decision	236 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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