FDA 510(k) Premarket Notification

K931305 ECLIPSE 3200 FOR USE IN UROLOGY APPLICATIONS

CLEARED

Jan 7, 1994
298 days to decision

K931305 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k931305/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 15, 1993
Decision date	Jan 7, 1994
Days to decision	298 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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