FDA 510(k) Premarket Notification

K934389 UROTEK LASER CATHETER

CLEARED

Feb 3, 1994
147 days to decision

K934389 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k934389/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 9, 1993
Decision date	Feb 3, 1994
Days to decision	147 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Energy Life Systems Corp.**
Location	Costa Mesa, CA, US
Contact	HANY HUSSEIN
510(k) history	5 submissions · 5 cleared · 1994-1995