FDA 510(k) Premarket Notification

K970808 MEDLITE IV Q-SWITCHED, FREQUENCY DOUBLED, ND:YAG LASER

CLEARED

Sep 5, 1997
184 days to decision

K970808 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k970808/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 5, 1997
Decision date	Sep 5, 1997
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Continuum Biomedical, Inc.**
Location	Mountain View, CA, US
Contact	LAURIE A RIDENER
510(k) history	19 submissions · 19 cleared · 1992-1999