FDA 510(k) Premarket Notification

K060304 PHOTEX DIODE LASER SERIES, MODELS 980, 810 AND 940

CLEARED

Mar 21, 2006
43 days to decision

K060304 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k060304/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 6, 2006
Decision date	Mar 21, 2006
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biotex, Inc.**
Location	Houston, TX, US
Contact	MATTHEW FOX
510(k) history	10 submissions · 10 cleared · 2006-2024