FDA 510(k) Premarket Notification

K050165 MODIFICATION TO IFL PROFESSIONAL SYSTEM, MODEL C100

CLEARED

Apr 19, 2005
84 days to decision

K050165 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k050165/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 25, 2005
Decision date	Apr 19, 2005
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cyden Limited**
Location	Swansea, Wales, GB
Contact	MICHAEL NOEL KIERNAN
510(k) history	21 submissions · 21 cleared · 2004-2024