FDA 510(k) Premarket Notification

K030423 POWERLITE 600 EP SYSTEM

CLEARED

May 9, 2003
88 days to decision

K030423 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k030423/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 10, 2003
Decision date	May 9, 2003
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Preswede AB**
Location	Great Neck, NY, US
Contact	SUSAN GOLDSTEIN FALK
510(k) history	2 submissions · 2 cleared · 2003-2004