FDA 510(k) Premarket Notification

K031805 BLU-U, MODEL 4170

CLEARED

Sep 9, 2003
90 days to decision

K031805 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k031805/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 11, 2003
Decision date	Sep 9, 2003
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dusa Pharmaceuticals, Inc.**
Location	Wilmington, MA, US
Contact	SCOTT LUNDAHL
510(k) history	2 submissions · 2 cleared · 2003-2004