FDA 510(k) Premarket Notification

K070353 KELSEY INTERSITITAL LASER THERAPY SYSTEM

CLEARED

May 2, 2007
85 days to decision

K070353 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k070353/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 6, 2007
Decision date	May 2, 2007
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kelsey, Inc.**
Location	Catonsville, MD, US
Contact	PAUL KETTERIDGE
510(k) history	1 submissions · 1 cleared · 2007-2007