FDA 510(k) Premarket Notification

K081612 AESCULIGHT FAMILY OF FLEXIBLE FIBERS, HANDPIECES AND TIPS FOR CO2 SURGICAL LASERS

CLEARED

Jun 25, 2008
16 days to decision

K081612 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k081612/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 9, 2008
Decision date	Jun 25, 2008
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Aesculight, LLC**
Location	Woodinville, WA, US
Contact	PAUL DIAZ
510(k) history	1 submissions · 1 cleared · 2008-2008