FDA 510(k) Premarket Notification

K082407 MODIFICATION TO ULTRALIGHT II ND: YAG LASER SYSTEM

CLEARED

Feb 3, 2009
166 days to decision

K082407 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k082407/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 21, 2008
Decision date	Feb 3, 2009
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sandstone Medical Technologies, LLC**
Location	Woodland, CA, US
Contact	MARK ROHRER
510(k) history	11 submissions · 11 cleared · 2004-2012