FDA 510(k) Premarket Notification

K093792 LED LIGHT SOURCE

CLEARED

Mar 18, 2010
98 days to decision

K093792 · Product code: **FCW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k093792/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Source, Fiberoptic, Routine (FCW)
Date received	Dec 10, 2009
Decision date	Mar 18, 2010
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sunoptic Technologies, LLC**
Location	Jacksonville, FL, US
Contact	JANICE G LEE
510(k) history	1 submissions · 1 cleared · 2010-2010