FDA 510(k) Premarket Notification

K152856 Helios III

CLEARED

Jun 2, 2016
247 days to decision

K152856 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k152856/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 29, 2015
Decision date	Jun 2, 2016
Days to decision	247 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Laseroptek Co., Ltd.**
Location	Torrance, CA, US
Contact	HONG CHU
510(k) history	13 submissions · 13 cleared · 2009-2025