FDA 510(k) Premarket Notification

K123293 PASTELLE Q-SWITCHED ND: YAG LASER

CLEARED

Apr 11, 2013
171 days to decision

K123293 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k123293/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 22, 2012
Decision date	Apr 11, 2013
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Won Technology Co., Ltd.**
Location	Woodinville, WA, US
Contact	Roberta Hines
510(k) history	1 submissions · 1 cleared · 2013-2013