FDA 510(k) Premarket Notification

K123842 LAWMAX DILATOR

CLEARED

Jun 24, 2013
193 days to decision

K123842 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k123842/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Dec 13, 2012
Decision date	Jun 24, 2013
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lifetech Scientific (Shenzhen) Co., Ltd.**
Location	Shanghai, CN
Contact	LILY SHI
510(k) history	3 submissions · 3 cleared · 2010-2013