FDA 510(k) Premarket Notification

K123640 TX1 TISSUE REMOVAL SYSTEM

CLEARED

Mar 20, 2013
114 days to decision

K123640 · Product code: **LFL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k123640/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ultrasonic Surgical (LFL)
Date received	Nov 26, 2012
Decision date	Mar 20, 2013
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tenex Health**
Location	Lake Forest,, CA, US
Contact	DAVID SALZBERG
510(k) history	1 submissions · 1 cleared · 2013-2013