FDA 510(k) Premarket Notification

K152922 ViziShot FLEX

CLEARED

Feb 19, 2016
140 days to decision

K152922 · Product code: **KTI** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k152922/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope Accessory (KTI)
Date received	Oct 2, 2015
Decision date	Feb 19, 2016
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spiration, Inc.**
Location	Redmond, WA, US
Contact	Cyndy J Adams
510(k) history	5 submissions · 5 cleared · 2015-2017