FDA 510(k) Premarket Notification

K163469 ViziShot 2 FLEX

CLEARED

Apr 6, 2017
115 days to decision

K163469 · Product code: **KTI** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k163469/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope Accessory (KTI)
Date received	Dec 12, 2016
Decision date	Apr 6, 2017
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Olympus Surgical Technologies America**
Location	Southborough, MA, US
Contact	Mary Anne Patella
510(k) history	12 submissions · 12 cleared · 2012-2024