FDA 510(k) Premarket Notification

K153306 Imbibe Needle

CLEARED

Dec 18, 2015
32 days to decision

K153306 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k153306/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Biopsy (KNW)
Date received	Nov 16, 2015
Decision date	Dec 18, 2015
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Orthovita, Inc.**
Location	Malver, PA, US
Contact	LYNN LUNDY
510(k) history	23 submissions · 23 cleared · 2001-2017