FDA 510(k) Premarket Notification

K153073 UroNav (Version 2.0)

K153073 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k153073/

CLEARED

Nov 16, 2015
25 days to decision

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Oct 22, 2015
Decision date	Nov 16, 2015
Days to decision	25 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Invivo Corporation**
Location	Pewaukee, WI, US
Contact	Kenneth Revennaugh
510(k) history	29 submissions · 29 cleared · 2005-2021

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k153073/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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