FDA 510(k) Premarket Notification

K133135 IMPAX VOLUME VIEWING 3.0

CLEARED

Mar 7, 2014
154 days to decision

K133135 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k133135/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Oct 4, 2013
Decision date	Mar 7, 2014
Days to decision	154 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Agfa Healthcare N.V.**
Location	Mortsel, BE
Contact	KOEN COBBAERT
510(k) history	27 submissions · 27 cleared · 2009-2025