FDA 510(k) Premarket Notification

CLEARED

K160328 DIVA ZSP2105CMI with QUBYX PerfectLum bundle

Feb 25, 2016
20 days to decision

K160328 · Product code: **PGY** · Radiology
Source: https://www.510kdatabase.net/k160328/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Diagnostic Radiology (PGY)
Date received	Feb 5, 2016
Decision date	Feb 25, 2016
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**The Linden Group Corp**
Location	Cedar Knolls, NJ, US
Contact	ROBERT COLAIZZO
510(k) history	2 submissions · 2 cleared · 2016-2020