FDA 510(k) Premarket Notification

K161130 ResolutionMD

CLEARED

Aug 24, 2016
125 days to decision

K161130 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k161130/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Apr 21, 2016
Decision date	Aug 24, 2016
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Calgary Scientific, Inc.**
Location	Calgary, Alberta, CA
Contact	Kyle Peterson
510(k) history	8 submissions · 8 cleared · 2006-2016