FDA 510(k) Premarket Notification

K173744 ProFuse CAD

CLEARED

Nov 21, 2018
349 days to decision

K173744 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k173744/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 7, 2017
Decision date	Nov 21, 2018
Days to decision	349 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Eigen**
Location	Nevada City, CA, US
Contact	William Mandel
510(k) history	16 submissions · 16 cleared · 1988-2023