FDA 510(k) Premarket Notification

K182464 PeekMed

CLEARED

Oct 25, 2018
45 days to decision

K182464 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k182464/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 10, 2018
Decision date	Oct 25, 2018
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Peek Health, S.A.**
Location	Braga, PT
Contact	Sara Silva
510(k) history	7 submissions · 7 cleared · 2018-2025