FDA 510(k) Premarket Notification

K251096 PeekMed web

CLEARED

Jul 14, 2025
95 days to decision

K251096 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k251096/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Apr 10, 2025
Decision date	Jul 14, 2025
Days to decision	95 days
Third-party review	No
Combination product	No
PCCP authorized	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