FDA 510(k) Premarket Notification

K232096 Transpara Density 1.0.0

CLEARED

Dec 11, 2023
151 days to decision

K232096 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k232096/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jul 13, 2023
Decision date	Dec 11, 2023
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Screenpoint Medical B.V.**
Location	Nijmegen, NL
Contact	Robin Barwegen
510(k) history	7 submissions · 7 cleared · 2018-2024