FDA 510(k) Premarket Notification

K210404 Transpara 1.7.0

CLEARED

Jun 2, 2021
112 days to decision

K210404 · Product code: **QDQ** · Radiology
Source: https://www.510kdatabase.net/k210404/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Lesions Suspicious For Cancer (QDQ)
Date received	Feb 10, 2021
Decision date	Jun 2, 2021
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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