FDA 510(k) Premarket Notification

K221347 Transpara 1.7.2

CLEARED

Aug 3, 2022
86 days to decision

K221347 · Product code: **QDQ** · Radiology
Source: https://www.510kdatabase.net/k221347/

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	May 9, 2022
Decision date	Aug 3, 2022
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	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