FDA 510(k) Premarket Notification

K193300 AIMI-Triage CXR PTX

CLEARED

Apr 8, 2020
133 days to decision

K193300 · Product code: **QFM** · Radiology
Source: https://www.510kdatabase.net/k193300/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Nov 27, 2019
Decision date	Apr 8, 2020
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Radlogics, Inc.**
Location	Los Gatos, CA, US
Contact	Moshe Becker
510(k) history	2 submissions · 2 cleared · 2012-2020

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US Lpp**
Contact	John J. Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov