FDA 510(k) Premarket Notification

K182177 Accipiolx

CLEARED

Oct 26, 2018
77 days to decision

K182177 · Product code: **QAS** · Radiology
Source: https://www.510kdatabase.net/k182177/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Aug 10, 2018
Decision date	Oct 26, 2018
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Maxq-AI , Ltd.**
Location	Tel Aviv, IL
Contact	Joshua Schulman
510(k) history	2 submissions · 2 cleared · 2018-2020