FDA 510(k) Premarket Notification

K223180 AIRAscore

CLEARED

Aug 25, 2023
318 days to decision

K223180 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k223180/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Oct 11, 2022
Decision date	Aug 25, 2023
Days to decision	318 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Airamed GmbH**
Location	T?bingen, DE
Contact	Maximilian Stalter
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Johner Institut GmbH**
Contact	Katharina Keutgen

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