FDA 510(k) Premarket Notification

K191623 ScanX Touch/ScanX Duo Touch

CLEARED

Aug 21, 2019
64 days to decision

K191623 · Product code: **MUH** · Radiology
Source: https://www.510kdatabase.net/k191623/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Jun 18, 2019
Decision date	Aug 21, 2019
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Air Techniques, Inc.**
Location	Hicksville, NY, US
Contact	Samir Ghevariya
510(k) history	18 submissions · 18 cleared · 1995-2019

REGULATORY CONSULTANT

Consulting firm	**Kamm & Associates**
Contact	Daniel Kamm

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