

K210820 EAGLE EDGE AXR90 and AXR120Aug 10, 2021
144 days to decisionK210820 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k210820/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Mar 19, 2021
Decision date	Aug 10, 2021
Days to decision	144 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Alliage S/A Industrias Medico Odontol?gica
Location	Recreio Ananguera, BR
Contact	Daniel Camargo
510(k) history	2 submissions · 2 cleared · 2021-2023

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](https://accessdata.fda.gov)

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