

K211688 DC-Air and Athlos-1 and Athlos-AirJul 22, 2021
50 days to decisionK211688 · Product code: **MUH** · Radiology
Source: <https://www.510kdatabase.net/k211688/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Jun 2, 2021
Decision date	Jul 22, 2021
Days to decision	50 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Athlos OY
Location	Espoo, FI
Contact	Konstantinos Spartiotis
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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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