

K213579 Stellaris 2D, Stellaris 2D Ceph, Stellaris 3D and Stellaris 3D CephMar 2, 2022
112 days to decisionK213579 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k213579/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Nov 10, 2021
Decision date	Mar 2, 2022
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fona S.R.L
Location	Assago, IT
Contact	Luigi Germano
510(k) history	4 submissions · 4 cleared · 2016-2022

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