

K222274 FONA XDCAug 23, 2022
25 days to decisionK222274 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k222274/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Jul 29, 2022
Decision date	Aug 23, 2022
Days to decision	25 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222274/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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