

**K231055 x-mind dc (under trademark Acteon), Owandy-RX DC  
(under trademark OwandyRadiology)**Dec 28, 2023  
259 days to decisionK231055 · Product code: **EHD** · Radiology  
Source: <https://www.510kdatabase.net/k231055/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Apr 13, 2023
Decision date	Dec 28, 2023
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>De G?tzen S.R.L.</b>
Location	Olgiate Olona, IT
Contact	Fabio Lissandrello
510(k) history	2 submissions · 2 cleared · 2021-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231055/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 26, 2026