

**K240059 FAgamin®**May 16, 2024  
129 days to decisionK240059 · Product code: **PHR** · Dental  
Source: <https://www.510kdatabase.net/k240059/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diammine Silver Fluoride Dental Hypersensitivity Varnish (PHR)
Date received	Jan 8, 2024
Decision date	May 16, 2024
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Tedequim Srl</b>
Location	C?rdoba, AR
Contact	Leonor Pasteris
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Compliance4Devices</b>
Contact	Juan Tezak

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240059/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026