

**K243522 ViVi® Toga Premium**May 30, 2025  
197 days to decisionK243522 · Product code: FYA · General Hospital  
Source: <https://www.510kdatabase.net/k243522/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Nov 14, 2024
Decision date	May 30, 2025
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Thi Total Healthcare Innovation GmbH</b>
Location	Feistritz Im Rosental, AT
Contact	Karl Hintermann
510(k) history	2 submissions · 2 cleared · 2023-2025

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Albert Rego PHD, Inc (D.B.A Rego Associates)</b>
Contact	Albert Rego

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

---

510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243522/> 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 13, 2026