FDA 510(k) Premarket Notification

CLEARED

K222214 ViVi® Surgical Helmet System (ViVi® Helmet, ViVi® Helmet HPL, ViVi® Hood)

Oct 17, 2023
449 days to decision

K222214 · Product code: **FXY** · General Hospital
Source: https://www.510kdatabase.net/k222214/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hood, Surgical (FXY)
Date received	Jul 25, 2022
Decision date	Oct 17, 2023
Days to decision	449 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Albert Rego, Ph.D. Consulting**
Contact	Albert Rego

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