May 30, 2025

THI Total Healthcare Innovation GmbH
% Albert Rego
Consultant
Albert Rego PhD, Inc (d.b.a Rego Associates)
25401 Cabot Road, # 122
Laguna Hills, California 92653

Re: K243522
Trade/Device Name: ViVi® Toga Premium
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FYA
Dated: April 30, 2025
Received: April 30, 2025

Dear Albert Rego:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

ALLAN GUAN -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection
Control Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243522

Device Name

ViVi® Toga Premium;
ViVi® Toga Premium XL-XXL (82220);
ViVi® Toga Premium M-L (82221);
ViVi® Toga Premium XXS-S (82222);
ViVi® Toga Premium XL-XXL (including customer logo) (82220V);
ViVi® Toga Premium M-L (including customer logo) (82221V);
ViVi® Toga Premium XXS-S (including customer logo) (82222V)

Indications for Use *(Describe)*

The ViVi® Toga Premium is a component of the ViVi® System and is intended to be worn by surgical personnel to provide a barrier between the operating environment and the surgical personnel in order to help protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K243522 510(k) SUMMARY

SUBMITTER:

THI Total Healthcare Innovation GmbH
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9181 Feistritz
Austria
Tel.: +43 4228 30100

SUBMITTER CONTACT:

Albert Rego, Ph.D. Inc.
25401 Cabot Road
Suite 122
Laguna Hills, CA 92653
Phone (949) 632-8126

DATE:

May 30th, 2025

TRADE NAME:

ViVi® Toga Premium

PRODUCT CODE / DEVICE:

FYA – Gown, Surgical

REGULATION NUMBER AND DESCRIPTION:

21 CFR 878.4040 – Surgical Apparel

PREDICATE DEVICE:

TotalShield™II Zippered Surgical Toga and Hood (K192194 cleared on October 15th,2019)

Reference Device:

ViVi® Surgical Helmet System (K222214 cleared on October 17th, 2024)

DEVICE DESCRIPTION:

The ViVi® Toga Premium is a one-piece head and body cover that is worn by healthcare professionals.
The ViVi® Toga Premium is a component of the ViVi® Surgical Helmet System and worn over the air-exchanging surgical helmet. The ViVi® Toga Premium is used with the ViVi® Helmet or the ViVi® Helmet HPL (High Power LED) with Light Emitting Diode (LED) light to provide a barrier between the operating environment and the surgical personnel to protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.

ViVi® Toga Premium is designed and has been tested to meet the applicable AAMI PB70 standards for level 4 compliance. The AAMI standard does not cover apparel for the head, face, and eyes. Therefore, the hood area and the lens are exempt from classification under this standard.

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STATEMENT OF INTENDED USE:

The ViVi® Toga Premium is a component of the ViVi® System and is intended to be worn by surgical personnel to provide a barrier between the operating environment and the surgical personnel in order to help protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.

COMPARISON TO PREDICATE:

The comparison of features and operation principles between ViVi® Toga Premium and predicate device *TotalShieldTM* II Zippered Surgical Toga and Hood (K192194) and reference device ViVi® Hood as part of the ViVi® Surgical Helmet System (Surgical Gown) (K222214) is listed as follows:

Category	Subject Device ViVi® Toga Premium (Surgical Gown)	Predicate Device TotalShield Surgical Helmet System (Surgical Gown)	Reference Device ViVi® Surgical Helmet System (Surgical Hood)	Comparison
Common Name	*ViVi® Toga Premium*	*TotalShield™* II Zippered Surgical Toga and Hood	ViVi® Surgical Helmet System	
Manufacturer	THI Total Healthcare Innovation Gmbh	Zimmer Surgical, Inc.	THI Total Healthcare Innovation Gmbh	
510(k) Number	K243522	K192194	K222214	
Registration Number	21 CFR 878.4040	21 CFR 878.4040	21 CFR 878.4040	Same
Device Class	Class II	Class II	Class II	Same
Product Code	FYA	FYA	FXY	Same as predicate device
Classification Panel	General Hospital	General Hospital	General Hospital	Same
Indication For Use[1]	The ViVi® Toga Premium is a component of the ViVi® System and is intended to be worn by surgical personnel to provide a barrier between the operating environment and the surgical personnel in order to help protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.	The TotalShield II Zippered Surgical Toga and/or TotalShield II Surgical Hood is for use with the TotalShield II Surgical Helmet and/or TotalShield Surgical Helmet with LED lighting as the TotalShield Surgical Helmet System that is intended to be worn by surgical personnel to provide a barrier between the operating environment and the surgical personnel in order to protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.	The ViVi® Hood is a component of the ViVi® System and is intended to be worn by surgical personnel to provide a barrier between the operating environment and the surgical personnel in order to help protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.	Same
Target user group	Surgical personnel	Operating Room Personnel	Surgical personnel	Similar
Condition of use Surgical Hood or Toga	Sterile / Disposable / Single Use	Sterile / Disposable / Single Use (Gowns)	Sterile / Disposable / Single Use (Gowns)	Same

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Category	Subject Device ViVi® Toga Premium (Surgical Gown)	Predicate Device TotalShield Surgical Helmet System (Surgical Gown)	Reference Device ViVi® Surgical Helmet System (Surgical Hood)	Similarities/Differences
Materials Technology Product Features				
Sterilization of Gown	Yes	Yes	Yes	Same
Sterilization method Surgical Hood or Toga	Ethylene oxide	Ethylene oxide	Ethylene oxide	Same
Sterilization Assurance Level (SAL)	10^{-6}	10^{-6}	10^{-6}	Same
Barrier Performance	ANSI/AAMI PB70:2012 Level 4 compliant ASTM F2407-06 (2013)	AAMI/ANSI PB70:2012 Level 4 compliant ASTM F2407-06 (Reapproved 2013) Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities	ASTM F2407-06 (2013)	Same
Method of Hood/Toga attachment to Surgical Helmet	Mechanical slot and hook and loop (Velcros®]	Hook-and-loop	Mechanical slot and hook and loop (Velcros®]	Similar
Material	SMS nonwoven with PE film	Base material SMS Nonwoven with PE Film reinforcement in critical zones	SMS nonwoven with PE film	Similar
Biocompatibility	ISO 10993-5 Cytotoxicity ISO 10993-10 Sensitization ISO 10993-23 Irritation	ISO 10993-5 Cytotoxicity ISO 10993-10 Sensitization ISO 10993-23 Irritation	ISO 10993-5 Cytotoxicity ISO 10993-10 Sensitization ISO 10993-23 Irritation	Same
Sizes	Toga: 3 sizes (XXL-XL; L-M; S-XXS)	Large, X-Large, 2X-Large, 3X-Large	Hood: single size	Similar

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NON-CLINICAL PERFORMANCE DESCRIPTION:

During the design and development of the ViVi® Toga Premium, the following tests were conducted and completed.

Level 4 liquid barrier performance according to:

ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities
ASTM Method F1671/F1671M Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

Biocompatibility according to:

ISO 10993-1 Biological evaluation of medical devices Evaluation and testing within a risk management process
ISO 10993-5 Biological Evaluation of Medical Devices - Part 5(2009): Tests for In Vitro Cytotoxicity
ISO 10993-10 Biological Evaluation of Medical Devices – Part 10(2021) Test for Skin Sensitization
ISO 10993-11 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
ISO 10993-23 Biological Evaluation of Medical Devices – Part 23(2021): Tests for Irritation)

Laser Resistance of surgical drapes according to:

ISO 11810 Lasers and laser-related equipment — Test method and classification for the laser resistance of surgical drapes and/or patient protective covers — Primary ignition, penetration, flame spread and secondary ignition

Tear Resistance according to:

ASTM D5587 Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure

Tensile test according to:

ASTM D5034 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)

Seam Strength according to:

ASTM F88/F88M Standard Test Method for Seal Strength of Flexible Barrier Materials

Lint and other particle generation according to:

ISO 9073-10:2005 Textiles — Test methods for nonwovens — Part 10: Lint and other particles generation in the dry state

Water Vapor Transmission according to:

ASTM E96/E96M-24A Standard Test Methods for Water Vapor Transmission of Materials

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PERFORMANCE COMPARISON TO PREDICATE

Property or Characteristics	**Test Method**	**Predicate Device TotalShield Surgical Helmet System (Surgical Gown)** K192194	**Subject Device ViVi® Toga Premium (Surgical Gown)** K243522
Flammability of clothing textiles	*16 CFR 1610*	Class 1 compliant PASS	Class 1 compliant PASS
Biological evaluation	ISO 10993-5 Cytotoxicity ISO 10993-10 Sensitization ISO 10993-23 Irritation	Compliant *PASS*	Compliant *PASS*
Tear Resistance	ASTM D5587	Compliant *PASS*	Compliant *PASS*
Tensile Strength	ASTM D5034	Compliant *PASS*	Compliant *PASS*
Seam Strength	ASTM F88/F88M	Compliant *PASS*	Compliant *PASS*
Laser Resistance	ISO 11810:2015	Compliant *PASS*	Compliant *PASS*
Linting	ISO 9073-10:2005	Compliant *PASS*	Compliant *PASS*
Water Vapor Transmission rate	ASTM E96	Compliant *PASS*	Compliant *PASS*
Barrier Performance	ANSI/AAMI PB70:2012	Compliant Level 4 PASS	Compliant Level 4 PASS

CLINICAL PERFORMANCE:

No clinical evaluation is necessary for this device.

CONCLUSION:

The conclusions drawn from the nonclinical tests demonstrate that the ViVi® Toga Premium is as safe, as effective, and performs as well as or better than the predicate device.