October 17, 2023

THI Total Healthcare Innovation GmbH
% Albert Rego
Consultant
Albert Rego, Ph.D. Consulting
25401 Cabot Road. Suite 122
Laguna Hills, California 92653

Re: K222214
Trade/Device Name: ViVi® Surgical Helmet System (ViVi® Helmet, ViVi® Helmet HPL, ViVi® Hood)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXY
Dated: September 21, 2022
Received: September 25, 2022

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.

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,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222214

Device Name
ViVi® Surgical Helmet System (ViVi® Helmet, ViVi® Helmet HPL, ViVi® Hood)

Indications for Use *(Describe)*
The ViVi® Hood is used with the ViVi® Helmet and/or ViVi® Helmet HPL as the ViVi® Surgical Helmet System 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® Helmet and ViVi® Helmet HPL has a battery powered fan, which provides a continuous flow of air in the the ViVi® Hood.
The ViVi® Hood is a stand-alone head covers that may be worn with a separate surgical gown. The ViVi® Hood, must be worn over a ViVi® Helmet or ViVi® Helmet HPL.

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.

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K222214

510(k) SUMMARY

(As required by 21 CFR 807.92)

I. SUBMITTER: Total Healthcare Innovation GmbH
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CONTACT: Albert Rego, Ph.D Inc.
Phone: (949) 632-8126

SUBMISSION DATE: October 15, 2023

II. DEVICE

TRADE NAME: ViVi® Surgical Helmet System (ViVi® Helmet, ViVi® Helmet HPL, ViVi® Hood)

COMMON NAME: Surgical Helmet System

CLASSIFICATION: Class II

PRODUCT CODE: FXY

III. PREDICATE DEVICES: Zimmer TotalShield™ Surgical Helmet System
510(k) Nr: K132386, Clearance date December 23rd, 2013

IV. DEVICE DESCRIPTION:

The ViVi® Surgical Helmet System is intended to be worn by surgical personnel to provide a barrier between the operating environment and the surgical personnel to help protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.
The ViVi® Surgical Helmet System is composed of sterile ViVi® Hood, which is used with the unsterile ViVi® Helmet or the unsterile 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.
The components include a top-covering sterile surgical hood (ViVi® Hood), an air-exchanging surgical helmet (ViVi® Helmet), and an air-exchanging surgical helmet with LED light (ViVi® Helmet HPL). The surgical hood is sterilized with Ethylene Oxide (EO). The surgical hood is worn over the helmets.
The unsterile accessories include a rechargeable Lithium Ion battery pack, a battery holster, a 1-bay battery charger, a 4-bay battery charger, and a non-sterile set of three foam pads (ViVi® Muffle).

Following table lists all reference numbers of the ViVi® Surgical Helmet System, including model, size dimensions, similarities, and differences.

Model/Reference number (REF)	Description	Size (if applicable)	Category name	Similarities / Differences
80100	ViVi® Helmet	One size	Surgical helmet	Design, materials and manufacturing technologies are similar. ViVi Helmet HPL includes a LED light
80130	ViVi® Helmet HPL	One size		
80200V	ViVi® Hood	One size	Surgical hood	N/A
60402	Battery Pack HW rechargeable Li-Ion Battery for ViVi® system	N/A	Rechargeable battery (Accessory)	N/A
60403	Battery Holster for Battery Pack	N/A	Battery holster (Accessory)	N/A
60501	1-bay Battery Charger for Battery Pack	N/A	Battery charger (Accessory)	N/A
60504	4-bay Battery Charger for Battery Pack	N/A		
60788	ViVi® Muffle (Foam pad set for ViVi® Helmet or ViVi® Helmet HPL)	One size	Foam pads (Accessory)	N/A

SURGICAL HOOD

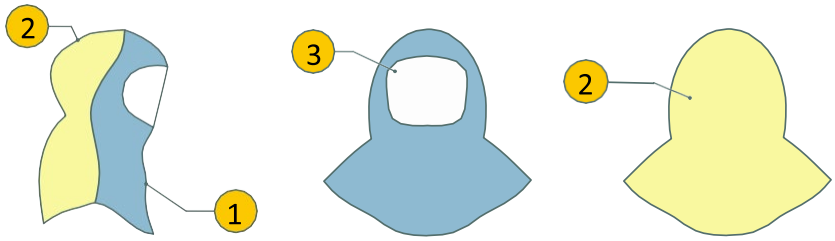
The ViVi® Hood is a one-piece head cover that is worn with a separate surgical gown, as shown in Picture 1. ViVi® Hood covers head and shoulders only. The blue SMS (Spunbond-Meltblown-Spunbond) nonwoven fabric is utilized throughout the hood.

The AAMI PB70 standard does not cover apparel from the head, face, and eyes. Therefore, the hoods and lens are exempt from classification under the AAMI PB70:2012 standard and contain no critical zones.

Picture 1: ViVi® Hood worn over ViVi® helmet without a surgical gown

SURGICAL HOOD PARTS AND MATERIALS

Picture 2 illustrates the parts of the ViVi® Hood. In the table materials corresponding to the positions are listed.



Picture 2: Illustration of positions and parts of ViVi® Hood

Serial number /Position	Part description	Material
①	Front panel	SMS nonwoven fabric
②	Vent	2-layer spunbond (PP)
③	Face Shield	Clear Polycarbonate

SURGICAL HOOD SPECIFICATION

The table shown below provides an overview of the ViVi® Hood specification.

Characteristic	Requirement	Test Method / Standard
Physical Specification		
Sizes	Hood: one size	NA
Resistance to tears and punctures	Tear Resistance compliant with ASTM D5587	ASTM D5587 Finished hood material sealed in sterile packaging with production equipment and procedure, double Sterilized, three non-consecutive lots
Fire protection	Compliant with 16 CFR-1610 class 1	16 CFR 1610 Finished hood material sealed in sterile packaging with production equipment and procedure, double sterilized. Three non-consecutive lots
Laser resistance	No ignition of SMS nowoven fabric	ISO 11810:2015 Finished hood material sealed in sterile packaging with production equipment and procedure, sterilized
Mechanical Specification		
Strength	Tensile Strength compliant with ASTM D5034	ASTM D5034 Finished hood material sealed in sterile packaging with production equipment and procedure, double sterilized
Durability	ViVi® Hood is single use devices	Labeling single use
Biological Specification		
Biocompatibility of material in contact with intact skin	No noticeable/will not elicit Irritation/Reaction	ISO 10993-10:2021 Test for skin sensitization ISO 10993-23:2021 Test for irritation (Intracutaneous reactivity) ISO 10993-5:2009 Test for in vitro cytotoxicity

SURGICAL HELMET

ViVi® Helmet is a non-sterile reusable surgical helmet covered with a sterile, single use surgical hood and is worn by healthcare professionals in the operating room during surgery. In addition, ViVi® Helmet also provides a support structure for ViVi® Hood and ensures positioning and fixation ViVi® Hood face shield on ViVi® Helmet. The ViVi® Helmet is also available with a battery-powered Light Emitting Diode (LED), ViVi® Helmet HPL.
Wearing ViVi® Hood in combination with a separate surgical gown will cause hot and humid exhaust air to get trapped in the suit. This effect is promoted by the high barrier performance of the textiles in use, which has the downside of high resistance against free airflow through the textile. Therefore, the ViVi® Helmet has a built-in battery-operated primary fan to push fresh air into the suit. A second integrated battery-operated air fan actively pushes air through a vent out of the suit avoiding recirculation of air. The air leaves the suit at the back of the healthcare professional, away from the patient (see Picture 3).

Picture 3: Airflow provided by ViVi® Helmet

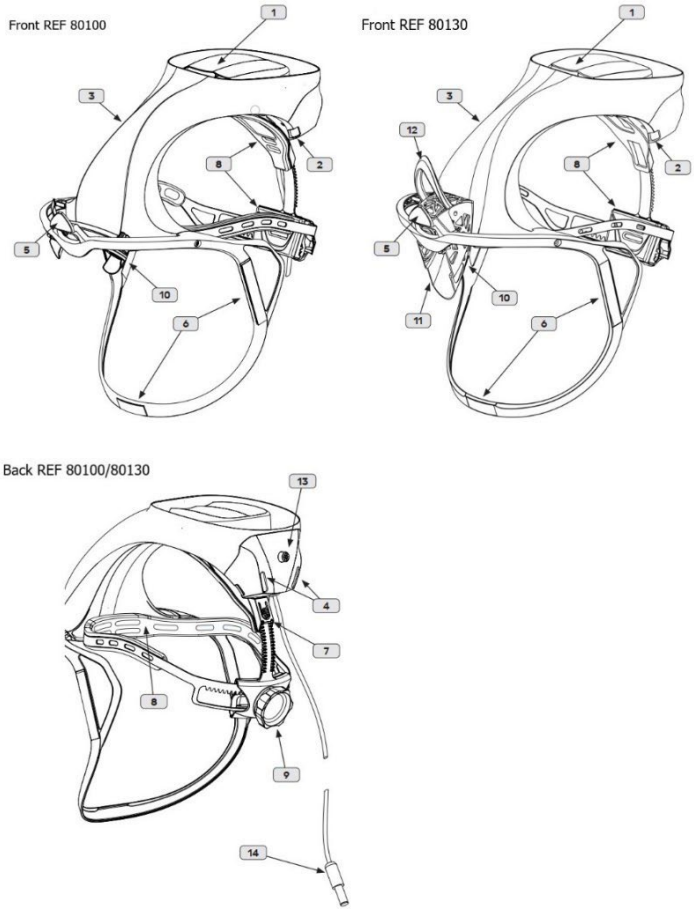
FOAM PADS (ViVi® Muffle)

ViVi® Helmet or ViVi® Helmet HPL contains three non-sterile foam pads named ViVi® Muffle (REF 50788) that are attached to the headband of the ViVi® helmet to increase user comfort. ViVi® Muffle consist of the garment (Lycra) and the foam (EVAC). The fabric encloses the foam. ViVi® Muffle consists of three components. The three components are identical in material, construct, and form, with the exception of the physical dimensions of these otherwise identical components They are replaceable if they are worn out or have to be changed due to hygienic reasons (e.g. sweating)

Picture 4: Position and contact areas of foam pads

SURGICAL HELMET PARTS AND MATERIALS

Picture 5 illustrates the parts of the ViVi® Helmet and ViVi® Helmet HPL. In the following table materials corresponding to the positions are listed.



Picture 5: ViVi® Helmet components

Serial number /Position	Part description	Material
1	Primary fan intake	Plastic
2	Exhaused air fan intake	Plastic
3	Air duct and structure to hold ViVi® Hood	Plastic
4	Exhaused air nozzle	Plastic
5	Frame for positioning face shield of ViVi® Hood	Plastic
6	Attachment points- Hook and Loop strip to fix face shield of ViVi® Hood	Nylon
7	Height adjustment strap	Plastic
8	Foam pads (ViVi® Muffle)	Lycra (garment) EVAC (foam)
9	Headband adjustment knob and adjustable headband	Plastic
10	Headlight- LED light (ViVi® Helmet HPL only)	Plastic, reinforced Plastic, copper, aluminum
11	Light housing	Plastic
12	Headlight adjustment handle	Plastic
13	Headlight control button	Plastic
14	Power cable	Copper / Silicon

SURGICAL HELMET SPECIFICATION

The table shown below provides an overview of the ViVi® Helmet / ViVi® Helmet HPL specification.

Characteristic	Requirement	Test Method/Standard
Physical Specification		
Air Quality	≤ 3°C temperature increase ≤5.000ppm CO_2 concentration (at ≤800ppm ambient concentration) No fogging of face shield	Internal Test method Temperature and CO_2 measurement inside dressed ViVi® Hood with ViVi® Helmet
Noise level	Less than predecessor product	Internal Test method Noise measurement with ViVi® Helmet and dressed ViVi® Hood (inside)
Operational Runtime	≥4 hours (without LED light)	Internal Test method Runtime test with ViVi® Helmet with Battery pack
Mechanical Specification		
Helmet weight	≤500g	Internal Test method ViVi® Helmet on calibrated scale
Gesture Control	Average score on five part rating scale ≥4 (good)	Internal usability study on dressed ViVi® System
Biological Specification		
Biocompatibility of material in contact with intact skin	No noticeable/will not elicit Irritation/Reaction	ISO 10993-10:2021 Test for skin sensitization ISO 10993-23:2021 Test for irritation (Intracutaneous reactivity) ISO 10993-5:2009 Test for in vitro cytotoxicity

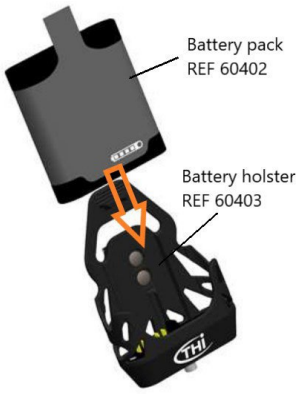
POWER SYSTEM

BATTERY PACK AND BATTERY HOLSTER

A rechargeable Lithium-ion (Li-ion) Battery pack provides the ViVi® Helmets with low voltage Direct Current (DC) electrical energy. The rechargeable Li-ion Battery pack is connected to the helmet via the battery holster and the helmet power cord (see Picture 5). The rechargeable Li-ion Battery pack is purchased off-the-shelf by THI and provided for use with ViVi® Surgical Helmet System

Picture 6: Power connection to helmet

The Battery holster serves as a receptacle for the Battery pack (see Picture 7). Additionally, the battery holster is used to fix the battery pack on users clothing (e.g. belt)



Picture 7: Battery pack and battery holster

CHARGING OF BATTERY PACK

To recharge and store the rechargeable Li-ion Batteries Pack two types of battery chargers are available as accessories to the ViVi® system. The charger is typically located in the scrub room of the operating theater and connected to the mains using a power plug

- Bay Charger (REF 60501)
  The 1- Bay Charger is intended to recharge one Battery pack. The charging bay is connected to a power supply which is connected to the mains with a power plug.
  The 1-Bay Charger is purchased off-the-shelf by THI and provided to charge Battery pack REF 60402

Picture 8: 1- Bay Charger

- 4- Bay Charger (REF 60504)
  The 4-Bay charger is intended to recharge four battery packs in parallel. The 4-Bay charger consists of four 1-Bay chargers (purchased off-the-shelf by THI as described above) which are built in a steel case. The 4-Bay charger is directly connected to the mains using a power plug.

Picture 9: 4- Bay Charger

BATTERY PACK AND CHARGER SPECIFICATION

The table below provides a summary of the battery and charger specification

REFERENCE NUMBER	60402	60501	60504
Product Description	Rechargeable Li-ion Battery pack	1-Bay Charger	4-Bay Charger
Original Manufacturer	RRC Power Solutions	RRC Power Solutions	--
Specification	Four cell Li-ion Battery pack	One bay charging module	Four bay charging module
Voltage/Capacity	14,4V /49,7Wh	Input:100-240VAC Output: 0-17,4VDC / 50W max.	Input:100-240VAC Output: 4x 0-17,4VDC / 4x 50W max.
Battery Life time	>7 hours with ViVi® Helmet >4 hours with ViVi® Helmet HPL (LED on)	N/A	N/A
Charging time	2,5 hours	N/A	N/A
Certifications	IEC 62133-2:2017 UN38.3	EN ISO 60601-1:2006/A1:2013 EN ISO 60601-1-2:2015 FCC 15 Class B cULus	EN ISO 60601-1:2006/A1:2013 EN ISO 60601-1-2:2015

V. INDICATIONS FOR USE:

The ViVi® Hood is used with the ViVi® Helmet and/or ViVi® Helmet HPL as the ViVi® Surgical Helmet System 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® Helmet and ViVi® Helmet HPL has a battery-powered fan, which provide a continuous flow of air in the ViVi® Hood.
The ViVi® Hood is a stand-alone head covers that may be worn with a separate surgical gown. The ViVi® Hood must be worn over a ViVi® Helmet or ViVi® Helmet HPL.

VI. INTENDED USE:

The ViVi® Surgical Helmet System 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.

VII. TECHNOLOGICAL CHARACTERISTICS:

Characteristic Hood	**Parameter / Value**
Personal Protective Equipment	EN 166:2011 Personal Eye Protection - High speed particles (45m/s) – low energy impact - Splashes of liquid
Face Shield – Field of View	>180°
Face Schield – Optical Quality (acc. EN166 cl. 7.1.2.1)	Class 1
Characteristic Helmet	**Parameter / Value**
Mass	13,1 [oz] / 370 [g]
Fanspeed (primary fan)	variable 3925 – 4775 rpm
Accessories – Battery/ Charger	**Parameter / Value**
Voltage (nominal)	14,4 [V] (DC)
Capacity (rated)	3.450[mAh]
Weight	8,1 [oz] / 230 [g]
Battery life	>7 [h] with ViVi® Helmet >4 [h] with ViVi® Helmet HPL
Charging time (typical)	2,5 [h]

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Category	Candidate Device ViVi® Surgical Helmet System K222214	Predicate Device TotalShield™ Surgical Helmet System , K132386	Comparison results
Common Name	ViVi® Surgical Helmet System	TotalShield™ Surgical Helmet System	
Manufacturer	THI Total Healthcare Innovation Gmbh	Zimmer Surgical Inc.	
510(k) Number	K222214	K132386	
Indication For Use	The ViVi® Hood is used with the ViVi® Helmet and/or ViVi® Helmet HPL as the ViVi® Surgical Helmet System 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 TotalShield Zippered Surgical Toga and/or TotalShield Surgical Hood is for use with the TotalShield Surgical Helmet and/or TotalShield Advanced Surgical Helmet with LED light 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.	Similar
Target user group	Surgical personnel	Surgical personnel	Same
Conditions of use Surgical Helmet	Non-sterile / reusable	Non-sterile / reusable	Same
Condition of use Surgical Hood	Sterile / Disposable / Single Use	Sterile / Disposable / Single Use	Same
System design / Operating principle	The ViVi® Hood has been designed to properly fit the ViVi® Helmet or ViVi® Helmet HPL in order to be used together as the ViVi® Surgical Helmet System. The ViVi® Hood is fastened to either the ViVi® Helmet or ViVi® Helmet HPL with hook-and-loop fasteners and a mechanical slot which ensures also the position of the lens. The device acts as a barrier between the operating environment and the surgical personnel	The *TotalShield* Zippered Surgical Toga has been designed to properly fit the *TotalShield* Surgical Helmet and Advanced Surgical Helmet with LED Lighting in order to be used together as the *TotalShield* Surgical Helmet System. The *TotalShield* Zippered Surgical Toga or Surgical Hood is fastened to either the TotalShield Surgical Helmet or Advanced Surgical Helmet with LED Lighting with aid of hook-and-loop fasteners and mechanical slot. The device acts as a barrier between the operating environment and the surgical personnel	Similar

Category	Candidate Device ViVi® Surgical Helmet System K222214	Predicate Device TotalShield™ Surgical Helmet System , K132386	Comparison result
Surgical gowns			
Sterilisation method Surgical Hood	Ethylene oxide	Ethylene oxide	Same
Sterilisation Assurance Level (SAL)	10^{-6}	10^{-6}	Same
Barrier Performance	Hood only Hood and lens are exempt from classification under AAMI PB70:2012	ASTM 2407-06 (2013) AAMI PB70 Level 3 compliant	Different
Material Front layer	SMS nonwoven with PE film	Single layer SMS nonwoven	Similar
Lens/Face Shield	Clear polycarbonate	PETG clear copolyester	Similar
Vent/Filter	Blended Synthetic Fiber Spunbound Polypropylene	Two-layer spunbond (Polypropylene)	Similar
Method of Hood attachment to Surgical Helmet	Mechanical slot and hook and loop	Mechanical slot and hook and loop	Same
Color	Blue	Blue	Same
Sizes	Hood: single size	Hood: single size Toga: 3 sizes (regular, large, extra large)	Same (for hood)
Surgical Helmet			
Air flow/conditioning	Air circulation provided by two integrated fans	Air circulation provided by integrated fan	Similar
Power supply	External Lithium-Ion battery pack connected by cable	External Lithium-Ion battery pack connected by cable	Same
Light option	Yes / LED light (ViVi Surgical Helmet HPL)	Yes / LED light (TotalShield Advanced Surgical Helmet)	Same
Helmet material	Plastic	Plastic	Same
LED Components	Plastic, reinforced Plastic, copper; aluminium	Aluminium, Stainless Steel	Different

IX. SUMMARY OF NON-CLINICAL TESTING

Laboratory testing regarding characteristics was performed on the ViVi® Surgical Helmet System to verify its safety and performance.

HELMET TESTING

Characteristics	Test Method /Standard	Acceptance Criteria	Test Result
Weight	Internal Test	≤ 500g (helmet)	PASS
Air Quality	Internal Test	≤ 3°C temperature increase ≤ 0% RH increase Below 5000 ppm CO2 concentration (at ≤ 800 ppm ambient concentration) No fogging of face shield	PASS
System Size	Internal Test	Significant lower crown line profile than predecessor product	PASS
Noise	Internal Test	Noise level ≤ predecessor product	PASS
Operational runtime	Internal Test	Battery runtime ≥4 hours (without LED light)	PASS
Gesture Control	Internal Usability Test	Average score for 'ease of use': ≥ "4-good" No score for 'ease of use' below "2-sufficient" Score table: 5 ('very good') – 1 ('not sufficient')	PASS

HOOD TESTING

Characteristics	Test Method /Standard	Acceptance Criteria	Test Result
Tear Resistance	ASTM D5587	>10 N	PASS
Tensile Strengh	ASTM D5034	>30 N	PASS
Fire protection Flammability of Clothing Textiles	16 CFR 1610	Fulfil requirements for Class 1	PASS
Laser resistance	ISO 11810:2015	No ignition	PASS
Ethylene Oxide residuals	ISO 10993-7:2008	EO: < 4mg/device ECH: < 9mg/device	PASS

X. BIOCOMPATIBILITY EVALUATION

As shown in the table below, the user contact with the system is isolated to the foam pads (ViVi® Muffle) and the hood material. All non-contacting devices and their materials are exempt from the requirements of ISO 10993-1 and will not be further evaluated due to the lack of contact to the user or patient.
This includes the ViVi Helmets with the exception of the foam pads (ViVi® Muffle) and the hood material.

Characteristics	Test Method /Standard	Acceptance Criteria	Test Result
Biocompatibility Foam Pads (ViVi® Muffle)	ISO 10993-10:2021 Test for skin sensitization ISO 10993-23:2021 Test for irritation (Intracutaneous reactivity) ISO 10993-5:2009 Test for in vitro cytotoxicity	Test for skin sensitization: Not sensitizing Test for irritation: No irritation Test for in vitro cytotoxicity: < grade2 (mild reactivity)	PASS
Biocompatibility Hood material (SMS nonwoven fabric)	ISO 10993-10:2021 Test for skin sensitization ISO 10993-23:2021 Test for irritation (Intracutaneous reactivity) ISO 10993-5:2009 Test for in vitro cytotoxicity	Test for skin sensitization: Not sensitizing Test for irritation: No irritation Test for in vitro cytotoxicity: <grade2 (mild reactivity)	PASS

XI. Summary of CLINICAL STUDY

The ViVi® Surgical Helmet System composed of VIVi® Helmet or ViVi® Helmet HPL and ViVi® Hood was not subjected to clinical testing.

XII. CONCLUSIONS

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device Zimmer TotalShield™ Surgical Helmet System (K132386)