November 21, 2024

Fink Engineering Pty Ltd
% Christy Foreman
Senior Consultant
Biologics Consulting
1555 King Street, Suite 300
Alexandria, Virginia 22314

Re: K240569
Trade/Device Name: FESL FINK Chamber; FEDL FINK Chamber; FETL FINK Chamber
Regulation Number: 21 CFR 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: Class II
Product Code: CBF
Dated: October 25, 2024
Received: October 25, 2024

Dear Christy Foreman:

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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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)*

K240569

Device Name

FESL FINK Chamber;
FEDL FINK Chamber;
FETL FINK Chamber

Indications for Use *(Describe)*

The conditions listed as appropriate for the use of HBO recognized by the Undersea & Hyperbaric Medical Society's (UHMS) Hyperbaric Oxygen Therapy Committee Report, as follows:

1. Air or gas embolism
2. Carbon monoxide poisoning and carbon monoxide poisoning complicated by cyanide poisoning
3. Clostridial myonecrosis and myonecrosis
4. Crush injuries, compartment syndrome, and other acute traumatic ischemias
5. Decompression sickness
6. Enhancement of healing of selected problem wounds
7. Exceptional blood loss anemia
8. Necrotizing soft tissue infections
9. Osteomyelitis (refractory)
10. Delayed radiation injuries (soft tissue and bony necrosis)
11. Compromised grafts and flaps
12. Acute Thermal Burn Injury
13. Intracranial abscess

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92 the 510(k) Summary for the FINK Hyperbaric Chambers (models FESL, FEDL, and FETL) is provided below.

1. SUBMITTER

Applicant:	Fink Engineering Pty Ltd 5 Delisser Place Queensland, Australia 4551 Email: fink@fink.com.au Phone: +61 7 5438 4900
Contact:	Eric Fink Managing Director Email: fink@fink.com.au Phone: +61 7 5438 4900
Submission Correspondent:	Christy Foreman Senior Consultant Biologics Consulting Group, Inc 1555 King Street, Suite 300 Alexandria, VA 22314 Email: cforeman@biologicsconsulting.com Phone: (301) 325-4245
Date Prepared:	February 26, 2024

2. DEVICE

Device Trade Name:	FINK Hyperbaric Chambers (models FESL, FEDL, and FETL)
Device Common Name:	Hyperbaric Chamber
Classification Name	21 CRF 868.5470 Hyperbaric chamber
Regulatory Class:	II
Product Code:	CBF

3. PREDICATE DEVICE

Predicate Device:	K031649 SL8/DL8/TL20 Hyperbaric Oxygen Treatment Facilities
Reference Device:	K152223 OxyHeal 5000 Rectangular Multiplace Hyperbaric Chamber

4. DEVICE DESCRIPTION

The FINK Hyperbaric Chamber is the rectangular pressure vessel that is identical in construction to the rectangular hyperbaric chambers covered by Fink's previously cleared K031649 which are all designed and built to meet the Safety Standard for Pressure Vessels for Human Occupancy ASME PVHO-1 and are certified accordingly. Chamber configurations vary depending upon the requirements set forth by the end user and supplied in the following configurations:

- Single Compartment - FESL
- Double Compartment – FEDL
- Triple Compartment – FETL

Patient capacities can range from four (4) to 28 twenty-eight (28) patients per chamber depending on the number of compartments required by the User. The pressure range for the individual compartments may also vary for the same reason with a minimum of 3.0 ATA to 6.0 ATA maximum allowable working pressures and design temperature range from 15ºC to 38ºC per compartment. The specific parameters for each chamber are defined by a User Design Specification which is approved by a Registered Professional Engineer in accordance with ASME PVHO-1. These chambers also comply with the National Fire Protection Agency (NFPA)

The chambers include the following features:

- Fire Protection
- Compressed air system
- Oxygen Delivery
- Environmental control system
- Unintended power supply
- Control Console

5. INTENDED USE/INDICATIONS FOR USE

It is the expressed, intended use of the FINK Hyperbaric Chambers (models FESL, FEDL, and FETL) to provide therapy to those patients with selected medical conditions that have been determined to respond to the application of hyperbaric oxygen. As a Class II prescriptive device, it is further intended for physician involvement in their procurement and routine use.

The UHMS is the professional medical organization chartered with setting the standards of care defining the appropriate use of hyperbaric oxygen. More specifically, the UHMS publishes a listing of medical conditions that have been clearly established as appropriate primary or adjunctive use hyperbaric oxygen (HBO). The disorders on the list have been scientifically validated and verified through extensive data collection. It should be noted that the list is dynamic. Based on the strength of the scientific data, disorders are both added and removed from the list, depending on the outcomes of scientific pursuit.

The conditions listed as appropriate for the use of HBO recognized by the Undersea & Hyperbaric Medical Society's (UHMS) Hyperbaric Oxygen Therapy Committee Report, as follows:

1. Air or gas embolism
2. Carbon monoxide poisoning and carbon monoxide poisoning complicated by cyanide poisoning
3. Clostridial myonecrosis and myonecrosis
4. Crush injuries, compartment syndrome, and other acute traumatic ischemias
5. Decompression sickness
6. Enhancement of healing of selected problem wounds
7. Exceptional blood loss anemia
8. Necrotizing soft tissue infections
9. Osteomyelitis (refractory)
10. Delayed radiation injuries (soft tissue and bony necrosis)
11. Compromised grafts and flaps
12. Acute Thermal Burn Injury
13. Intracranial abscess

6. SUBSTANTIAL EQUIVALENCE

Comparison of Intended Use and Indications for Use

The intended use of the predicate device, the reference device and the proposed device are identical. The indications for use are all derived from the Undersea and Hyperbaric Medical Society recommendations for HBOT. The indications for use of the subject and predicate device are identical. The indications of use of the predicate device is a subset of the indications for use of the reference device.

Technological Comparisons

The table below compares the key technological feature of the subject devices to the predicate device (K031649 SL8/DL8/TL20 Hyperbaric Oxygen Treatment Facilities).

Table 1: Technological Comparison

	Proposed Device	**Predicate Device**	**Discussion**
510(k) Number	K240569	K031649	N/A
Applicant	Fink Engineering PTY LTD	Fink Engineering PTY LTD	Same
Device Name	Fink Engineering Chamber Systems Series (Fink Chamber)	Fink SL8/DL8/TL20	N/A
Classification Regulation	21 CFR 868.5470	21 CFR 868.5470	Same
Product Code	CBF	CBF	Same

	Proposed Device	Predicate Device	Discussion
Indications for Use	As defined by the Undersea & Hyperbaric Medical Society Hyperbaric Oxygen Therapy Committee	As defined by the Undersea & Hyperbaric Medical Society Hyperbaric Oxygen Therapy Committee	Same
Compartments	FESL = 1 FEDL = 2 FETL = 3	SL8 = 1 DL8 = 2 TL20 = 3	Same
Compartment Interior Vol	~586 ft^3 - ~4200 ft^3	~586 ft^3 - ~2546 ft^3	Equivalent Multiplace chambers are ordered to customer specifications. Each chamber is tested to PVHO to ensure that the construct of the chamber meets industry requirements. The same materials are used for construction and the maximum pressure is identical. Size of the chamber was expanded. The volume went from 72SCM to 119 SCM for the FETL chamber. Testing demonstrates applicable standards are met.
Patient Capacity	FESL = up to 8 FEDL = up to 8 FETL = up to 28	SL8 = up to 8 DL8 = up to 8 TL20 = up to 20	Patient capacity for a chamber may vary depending on contract requirements
Weight	~15,432 lbs – ~145,000lbs	~15,432 lbs – ~110,231 lbs	Equivalent. Weight varies with patient capacity
Operating Pressure	Up to 6.0 ATA (73.5 psig)	Up to 6.0 ATA (73.5 psig)	Same
Operating Temperature	59˚F -100˚F	62˚F -100˚F	Equivalent The slight modification in operating temperature does not raise new or different questions of safety and effectiveness.
Pressure Control Scheme	PLC with manual backup	Electropneumatic with manual backup	Equivalent The addition of the PLC control with manual back is the same as Reference Device K152223 OxyHeal 5000 Rectangular Multiplace Hyperbaric Chamber. The PLC change does not raise new or different questions of safety and effectiveness. Software testing and performance testing have been conducted in support of the modification.
Pressurization Rate (Max)	1 ft/sec	1 ft/sec	Same

	Proposed Device	Predicate Device	Discussion
Pressurization Measurement	Digital & analog	Digital & analog	Same
Emergency Decompression Rate	27.5 ft/min to achieve minimum decompression time of 6 minutes or less from 6 ATA IAW NFPA 99, 20.2.4.5.1, 2005 Ed.	27.5 ft/min to achieve minimum decompression time of 6 minutes or less from 6 ATA IAW NFPA 99, 20.2.4.5.1, 2002 Ed.	Same. The subject device adheres to a more current version of the same standard.
Normal Ventilation Rate	3 scfm IAW NFPA 99, 20.2.4.1.1, 2005 Ed	3 scfm IAW NFPA 99, 20.2.4.1.1, 2002 Ed	Same.
Chamber Lighting	External – dimmable	External - dimmable	Same. The subject device adheres to a more current version of the same standard.
Medical Transfer Lock	Yes	Yes	Same
Backup Electrical Power	UPS	UPS	Same
Communications	PA System with Patient Entertainment - sound powered backup. Wireless is optional	PA System with Patient Entertainment - sound powered backup. Wireless is optional	Same
CCTV	Yes	Yes	Same
Viewports	Circular (3-9) Minimum - one per compartment Minimum size - Ø6" Maximum size - Ø30" FESL = 1-3 FEDL = 2-4 FETL = 3-9	Circular (3-9) Minimum - one per compartment Minimum size - Ø6" Maximum size - Ø30" SL8 = 1-3 DL8 = 2-4 TL20 = 3-9	Same.
Auxiliary Penetrators	Yes	Yes	Same

	Proposed Device	Predicate Device	Discussion
Built in Breathing Systems (BIBS) with Oxygen Overboard Dump	Yes FESL = 2 min per compartment FEDL = 2 min per compartment FETL = 2 min per compartment	Yes SL8 = 2 min per compartment DL8 = 2 min per compartment TL20 = 2 min per compartment	Equivalent Allows for each Attendant to be fully supported. Piping and controls remain the same. BIBS are for Attendants only. Terminology in prior submissions used the term BIBS interchangeably for patients and for attendants. However, current preference is to indicate BIBS is for the attendant and the hood is for the patient.
Patient Hood System with Oxygen Overboard Dump	Yes FESL = up to 8 FEDL = up to 8 FETL = up to 28	Yes SL8 = 8 DL8 = 8 TL20 = 22	Equivalent Allows for each patient to be fully supported. Piping and controls remain the same. Refer to the row "Patient Capacity" above.
Emergency Breathing Air Crossover	Yes	Yes	Same
Medical Suction	Yes	Yes	Same
Door Style	Rectangular	Rectangular	Same
Deluge Fire Suppression System (FSS)	Yes, IAW NFPA 99, Ch 20, 2005 Ed	Yes, IAW NFPA 99, Ch 20, 2002 Ed	Equivalent. The subject device adheres to a more current version of the same standard.
FSS Audio/visual Alarm	Yes	Yes	Same
Environmental Control	Yes (Heating & Cooling)	Yes (Heating & Cooling)	Same
Temperature & Humidity Monitoring	Yes (Digital)	Yes (Digital)	Same
Air Supply	Oil-free, Low-Pressure compressor	Oil-free, Low-Pressure compressor	Same
Backup Air Supply	Yes	Yes	Same
Air Supply Filtration	Yes/Coalescing and Active Carbon	Yes/Coalescing and Active Carbon	Same
Air & CO Analysis	Yes	Yes	Same
Low Pressure Air Distribution	Yes	Yes	Same
Gas Distribution Panel	Yes	Yes	Same
Gas Monitoring	Yes (Oxygen & CO_2)	Yes (Oxygen & CO_2)	Same

	Proposed Device	Predicate Device	Discussion
Emergency Breathing Air At Operator Console	Yes	Yes	Same
Optional Patient Toilet & Sink	Yes	Yes	Same
Optional Medical Sink	Yes	Yes	Same

The addition of the PLC control with manual back is the same as the reference device. This type of control mechanism change has been implemented in a number of 510(k) submissions. The PLC change does not raise new or different questions of safety and effectiveness. The change can be supported with data. The OxyHeal device is cited as a reference device to support the test methods which is primarily software verification and validation.

Other minor changes have been also been supported with the appropriate supportive testing and do not raise new issues of safety or effectiveness.

7. PERFORMANCE DATA

Biocompatibility Testing

As the hyperbaric chamber is dry gas pathway contacting only, it was evaluated in accordance with ISO 18562-1: 2017 and tested for particulate matter and volatile organic compounds (VOCs). A toxicological risk assessment was also conducted.

Electrical safety and electromagnetic compatibility (EMC)

The Fink Hyperbaric Chambers were assessed for conformity with the relevant requirements of the following standards and found to comply:

- ANSI/AAMI ES 60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: electromagnetic disturbances – Requirements and tests.
- IEC 61000-4-3:2010 - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 3: Radiated, radiofrequency, electromagnetic field immunity test – Proximity Fields, Table 9
- IEC 61000-4-39:2017- Electromagnetic Compatibility (EMC) -- Part 4-39: Testing And Measurement Techniques - Radiated Fields In Close Proximity - Immunity Test, Table 11
- ETSI TS 138 101-1 V17.5.0 (2022-05)

- IEC 60601-1-8:2006, AMD1:2012, AMD2:2020 - Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- ANSI C63.27-2021 American National Standard for Evaluation of Wireless Coexistence
- AAMI TIR69:2017 (R2020) Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions." Enhanced documentation was provided since a failure or flaw of any device software function(s) could present a hazardous situation with a probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use.

Bench Testing

The following testing and /or examinations were used in whole or in part for certifying the weld integrity and the integrity of the entire pressure vessel for human occupancy (PVHO) (the hyperbaric chamber):

- Penetrant Examination (PE)
- Ultrasonic Testing (UT)
- Radiographic Examinations (RT)
- Magnetic Particle Examination (MT)

The following additional tests were also performed:

- Hydrostatic testing
- Chamber pneumatic test
- Chamber Relief Valve testing
- Air quality testing
- Max Pressurization Rate
- Maximum Depressurization Rate
- Treatment Pressure Profiles
- Functional test - Uninterrupted Power Supply (UPS)
- Functional test - Medical Lock
- Functional test - Lighting
- Functional test - Hoods/BIBS Circuits
- Functional test- Gas Analysis
- Functional test - Communications
- Functional test - CCTV
- Functional test - Environmental Control System (ECS)
- Functional test - Entertainment

- Functional test - Sanitary system
- Functional test - Fire Suppression System (FSS)
- Functional test - Handheld Deluge (HHD)
- Functional test - Nurse call
- Functional test - Emergency Breathing Air at Console
- Functional test - Wi-Fi Cyberattack - Windows
- Functional test - Wi-Fi Cyberattack - FEGen4
- Functional test - Wi-Fi Cyberattack- FEGen4
- Functional test - Cyberattack - Ethernet
- Functional test - Cyberattack - Bluetooth
- Functional Test - All Stop
- Functional Test - Soft All Stop
- Functional Test - Hardware verification
- Functional Test - Alarms
- Functional Test - CPU & Memory test

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Data

Not applicable. Clinical studies are not necessary to establish the substantial equivalence of this device.

8. CONCLUSION

Based on the detailed comparison between the predicate devices and the subject devices, the performance testing and conformance with applicable standards, the Fink Chamber can be found substantially equivalent to the predicate device.