



January 15, 2026

Bridge to Life Ltd.
% Michael Nilo
President and Principal Consultant
Nilo Medical Consulting Group
3706 Butler St. #313
Pittsburgh, Pennsylvania 15201

Re: DEN250009

Trade/Device Name: VitaSmart Hypothermic Oxygenated Perfusion System

Regulation Number: 21 CFR 876.5881

Regulation Name: Hypothermic machine perfusion system and accessories for orthotopic liver transplant

Regulatory Class: Class II

Product Code: SGY

Dated: March 29, 2025

Received: March 31, 2025

Dear Michael Nilo:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the VitaSmart Hypothermic Oxygenated Perfusion System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

The VitaSmart Hypothermic Oxygenated Perfusion (HOPE) System is intended to be used for hypothermic oxygenated perfusion of donor livers, after a period of static cold storage (SCS), for eventual transplantation into a recipient. The VitaSmart HOPE System is not intended to be used while the organ is in transport.

The device is indicated for use with Donation after Brain Death (DBD) donor livers ≤ 65 years old; or Donation after Circulatory Death (DCD) donor livers ≤ 55 years old and with ≤ 18 minutes of functional warm ischemic time with macrosteatosis $\leq 10\%$.

The VitaSmart HOPE System is intended for use by qualified healthcare professionals trained in the use of the VitaSmart HOPE System.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the VitaSmart Hypothermic Oxygenated Perfusion System, and substantially equivalent devices of this generic type, into Class II under the generic name hypothermic machine perfusion system and accessories for orthotopic liver transplant.

FDA identifies this generic type of device as:

Hypothermic machine perfusion system and accessories for orthotopic liver transplant. A hypothermic machine perfusion system and accessories for orthotopic liver transplant is a device that performs oxygenated perfusion of liver grafts at sub-physiological temperatures until it is transplanted into a recipient patient. This generic type of device may also include perfusion sets, oxygenators, and other components of the perfusion circuit.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On March 31, 2025, FDA received your De Novo requesting classification of the VitaSmart Hypothermic Oxygenated Perfusion System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the VitaSmart Hypothermic Oxygenated Perfusion System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the VitaSmart Hypothermic Oxygenated Perfusion System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	Mitigation Measures
Graft failure or organ damage due to: <ul style="list-style-type: none"> • Improper organ perfusion pressure or temperature, • Insufficient priming of the perfusion circuit or • Improper preparation of the perfusion circuit with liver graft • Compromised perfusion or perfusion monitoring during handling 	Clinical performance testing Non-clinical performance testing Software verification, validation, and hazard analysis Human factors testing Labeling

Infection	Sterilization validation Reprocessing validation Training Shelf life testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
Delayed procedure or graft damage due to interference with other devices or electrical hazards	Electromagnetic compatibility (EMC) testing Electrical safety testing

In combination with the general controls of the FD&C Act, the hypothermic machine perfusion system and accessories for orthotopic liver transplant is subject to the following special controls:

- (1) Clinical performance testing must demonstrate that the device performs as intended when used with a compatible perfusion solution, and must evaluate:
 - (i) Organ graft function and survival;
 - (ii) Recipient survival; and
 - (iii) Device-related adverse events, including ischemic and vascular complications and perfusion injury.
- (2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:
 - (i) Mechanical integrity and reliability of the perfusion circuit; and
 - (ii) Controls and monitors for the perfusion parameters including temperature, pressure, flow, and oxygenation.
- (3) Software verification, validation, and hazard analysis must be performed.
- (4) The organ-contacting components of the device must be demonstrated to be biocompatible.
- (5) Performance data must demonstrate the sterility of all organ-contacting components of the device.
- (6) Performance data must support the shelf-life by demonstrating package integrity, continued sterility, and functionality of the organ-contacting components of the device.
- (7) Performance data must demonstrate the electromagnetic compatibility and electrical safety of the device in the intended use environment, including environments encountered during organ transport.
- (8) Human factors validation testing must demonstrate that the intended user(s) in the intended use environment can correctly and safely use the device based solely on the directions for use and training program.
- (9) A training program must be included with sufficient educational elements so that upon completion of the training program, the user can correctly prepare, perfuse, and monitor the organ while mitigating the risk of contamination.
- (10) Labeling must include:
 - (i) The recommended training required for the safe use of the device;
 - (ii) Information on compatible perfusion solutions;
 - (iii) Information on the organ donor and recipient population from which the device performance was evaluated.
 - (iv) Information on the perfusion protocols and configurations from which the device performance was evaluated;

- (v) A list of all accessories and components; and
- (vi) A shelf life or service period.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the hypothermic machine perfusion system and accessories for orthotopic liver transplant they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 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>.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Virag Patel at 301-796-0452 or virag.patel@fda.hhs.gov.

Sincerely,

Glenn B. Bell, Ph.D.
Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health