August 10, 2021

HyTek Medical, Inc.
% Allison Komiyama
Principal Consultant
AcKnowledge Regulatory Strategies LLC
2251 San Diego Ave Suite B-257
San Diego, California 92110

Re: K201026
Trade/Device Name: sOLVe Tube
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: Class II
Product Code: CBI
Dated: July 13, 2021
Received: July 15, 2021

Dear Allison Komiyama:

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 (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 located 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.

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 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201026

Device Name
sOLVe Tube™

Indications for Use *(Describe)*
The sOLVe Tube™ is used to isolate the left or the right lung of a patient for surgery, one lung ventilation or one lung anesthesia.

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.

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HyTek Medical, Inc.

510(k) Summary
K201026

DATE PREPARED
August 5, 2021

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DEVICE INFORMATION

Proprietary Name/Trade Name:	sOLVe Tube™
Common Name:	Tube, Tracheal/Bronchial, Differential Ventilation (w/wo connecter)
Regulation Number:	21 CFR 868.5740
Class:	Class II
Product Code:	CBI
Premarket Review:	Anesthesiology
Review Panel:	ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Device (DHT1C)

PREDICATE DEVICE IDENTIFICATION
The sOLVe Tube™ is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K051522	Silbroncho® Tubes / Fuji Systems Corporation	✓

The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION
The Simple One Lung Ventilation for Everyone (sOLVe) Tube is a single use dual lumen endobronchial tube (DLT) intended for lung isolation and for lung ventilation by healthcare professionals (HCP) in hospitals. The sOLVe Tube can function as both a left-sided and a right-sided DLT. The distal tip of the tube will fit in either the left or right mainstem bronchus.

The sOLVe Tube is packaged and provided to the HCP as a kit. The kit includes the following components:

1. sOLVe Tube with pre-installed pliable aluminum 10Fr intubation stylet
2. Dual Bronchoscopy Swivel adapter with integrated safety clamp
3. Haider TubeGuard endotracheal tube holder/bite block with strap
4. Soft suction catheters
5. Two syringes (3 mL and 10 mL)

The sOLVE tube is intended for an adult population only.

INDICATIONS FOR USE

The sOLVe Tube™ is used to isolate the left or the right lung of a patient for surgery, one lung ventilation or one lung anesthesia.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

HyTek believes that the sOLVe Tube is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar design and dimensions and uses similar or identical materials as the device cleared in K051522. The subject device is uniquely designed so that it can function as both a left-sided and a right-sided DLT and includes additional safety features (i.e., ridges on the balloons to prevent balloon slippage that can lead to DLT dislodgement). The subject device has the same intended use and similar technological characteristics (maximum inflation volumes, suction catheter diameters, and design features) to the device cleared in K051522. These technological characteristics have undergone testing to ensure the device is as safe and effective as the predicate.

The technological characteristics of the subject device and the predicate device are summarized in the table below.

	Subject Device	***Predicate Device***
	sOLVe Tube™ K201026	Silbroncho® Tubes K051522
Indications for Use	The sOLVe Tube™ is used to isolate the left or the right lung of a patient for surgery, one lung ventilation or one lung anesthesia	The Silbroncho® is used to isolate the left or the right lung of a patient for surgery, one lung ventilation or one lung anesthesia
Product Code	CBI	CBI
Regulation Number	21 CFR 868.5740	21 CFR 868.5740
Technological characteristics		
Design Features	• Double lumen shaft with stylet • Tracheal balloon • Endobronchial balloon • Swivel connector with Carlens Y adapter	• Double lumen shaft with stylet • Tracheal cuff • Endobronchial cuff • Swivel connector with Carlens Y adapter

	Subject Device	***Predicate Device***
	sOLVe Tube™ K201026	Silbroncho® Tubes K051522
Sizes	Device available in 1 size: 35Fr	Device available in 4 distinct sizes: 33Fr, 35Fr, 37Fr, and 39Fr
Tube O.D.	13 mm	33Fr: 9.5 – 12.3 mm 35Fr: 10.0 – 13.3 mm 37Fr: 10.5 – 14.3 mm 39Fr: 11.0 – 15.3 mm
Recommended bronchoscope O.D.	Tracheal lumen: ≤ 6.0 mm Bronchial lumen: ≤ 5.0 mm	Sizes 33 and 35Fr: ≤ 3.1 mm Sizes 37 and 39Fr: ≤ 4.0 mm
Maximum Inflation Volumes	Endobronchial balloon: < 5 mL Tracheal balloon: < 10 mL	Endobronchial cuff: 4.5 – 7 mL Tracheal cuff: < 10 mL
Suction Catheter Diameter	10Fr	8Fr, 12Fr
Main Materials of Composition	silicone, polypropylene	silicone, polyethylene
Sterilization	Sterile	Sterile
Sterilization method	Ethylene Oxide	Ethylene Oxide

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the sOLVe Tube.

The sOLVe Tube includes components that come in contact with the patient during use. The dual lumen component and the T-type suction catheters were evaluated as external communicating devices with limited duration (≤ 24 hours) with mucosal membrane. Biocompatibility testing included cytotoxicity testing per ISO 10993-5, irritation testing per ISO 10993-10, sensitization testing per ISO 10993-10, acute systemic toxicity testing per ISO 10993-11, VOC emissions and toxicity per ISO 18562-3, particulate matter analysis per ISO 18562-2, and bacterial endotoxin testing per ANSI/AAMI ST72.

The following tests were performed to demonstrate equivalence to the predicate device:

- Performance testing (Bench)
  - Determination of Cuff Diameter (per ISO 5361)
  - Resistance to Cuff Tube Collapse (per ISO 5361)
  - Resistance to Cuff Herniation (per ISO 5361)
  - Cuff Tracheal Seal (per ISO 5361)
  - Resistance to Kinking of Main Shaft and Distal Bronchial Shaft (per ISO 5361)
  - Cuff Compliance Leak Test (per ISO 5361)
  - Determination of Dual Lumen Tube Lumen Internal Diameter (per ISO 16628)
  - Radio-opacity Test (ASTM F640)
  - Balloon Bench Testing
  - Membrane Durability Test

    - Bronchoscope Insertion Test
    - Double Clamp Operation
    - Cadaver Trial to test the Universal Design
- Performance Testing (Animal)
    - Ease of Insertion
    - Performance of the Tracheal and Bronchial Balloon
    - Success of Lung Isolation and One Lung Ventilation

The results of these tests support the substantial equivalence of the sOLVe Tube to the predicate device.

CONCLUSION

The subject device and the predicate device have the same intended use, and based on the testing performed, including non-clinical performance testing (bench and animal), it can be concluded that the differences in technological features do not raise different questions of safety and effectiveness. The similar indications for use, technological characteristics, and performance characteristics for the proposed sOLVe Tube are assessed to be substantially equivalent to the predicate device.