May 3, 2021

Ambu A/S
% Sanjay Parikh
Director, QA/RA
Ambu Inc.
6230 Old Dobbin Lane, Suite 250
Columbia, Maryland 21045

Re: K203749
Trade/Device Name: Ambu VivaSight 2 DLT, Ambu VivaSight 2 Adapter Cable
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: Class II
Product Code: CBI
Dated: March 29, 2021
Received: March 30, 2021

Dear Sanjay Parikh:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203749

Device Name
Ambu VivaSight 2 DLT

Indications for Use *(Describe)*
Intubation with Ambu VivaSight 2 DLT is indicated for patients with pathological lung conditions or other medical conditions that require endobronchial intubation, mechanical ventilation and isolation of one lung from the other, e.g. for thoracic surgery.

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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510(k) Summary – Ambu® VivaSight™ 2 DLT

This 510(k) summary has been prepared in accordance with 21 CFR 807.87(h) and the content and format of the 510(k) summary has been prepared in accordance with 21 CFR 807.92.

Submitter	Ambu A/S Baltorpbakken 13 2750 Ballerup Denmark Tel.: +45 7225 2000 Fax.: +45 7225 2050
Contact Person	Name: Karina Matthiesen Job Title: Senior Regulatory Affairs Professional Address: Ambu A/S, Baltorpbakken 13, 2750 Ballerup Email: kama@ambu.com Telephone number: +45 7225 2000 Fax number: +45 7225 2050
Date Summary Prepared	March 26, 2021
Device Trade Name	Ambu® VivaSight™ 2 DLT Accessory: Ambu® VivaSight™ 2 Adapter Cable
Device Common Name	Double-lumen endobronchial tube
Device Classification	Tracheal/bronchial differential ventilation tube Product Code: CBI 21 CFR 868.5740 Class II
Predicate device	Substantial equivalence to the following legally marketed device is claimed: K181886 VivaSight-DL™, ETView Ltd.

Device Description	Ambu VivaSight 2 DLT is a sterile, single-use, left-sided, double-lumen endobronchial tube with an embedded video camera and light source at the distal end of the tracheal lumen and integrated video cable with video connector. The embedded video camera is used for visualization during the intubation procedure and to verify the tube placement. The picture is shown on an Ambu displaying unit, which Ambu VivaSight 2 DLT is connected to via Ambu VivaSight 2 Adapter Cable. Ambu VivaSight 2 Adapter Cable is a non-sterile, single patient use accessory to Ambu VivaSight 2 DLT. Ambu VivaSight 2 DLT is connected to and powered by an Ambu displaying unit via Ambu VivaSight 2 Adapter Cable; the whole system is referred to as the VivaSight 2 DLT system. Ambu VivaSight 2 DLT is indicated for left or right lung isolation and use as a temporary artificial airway in adults requiring mechanical one-lung ventilation and is fitted with a stylet to enable shaping of the tube for navigation during intubation. A colorless tracheal cuff provides sealing against tracheal wall and the corresponding pilot balloon indicates state of cuff inflation/deflation Similarly, a blue bronchial cuff provides sealing against bronchial wall and the corresponding pilot balloon indicates state of cuff inflation/deflation. A flush line with flush exits next to the camera lens ensures possibility for cleaning of the camera lens. Ambu VivaSight 2 DLT can be connected to ventilation equipment via a Y-connector, which is included with the product. The Y-connector is sterile, single-use. The Y-connector caps enable lung deflation and use of accessories such as bronchoscopes and suction catheters in Ambu VivaSight 2 DLT. Furthermore, valves on the Y-connector enables opening and closing of the ventilation flow to each of the tracheal and bronchial lumens. The Y-connector airway tubes are colour coded to indicate tracheal and bronchial connection. Ambu VivaSight 2 DLT will be available in four sizes: 35 Fr, 37 Fr, 39 Fr, and 41 Fr.
Intended Use	Ambu VivaSight 2 DLT is a sterile, single-use, double-lumen endobronchial tube intended to be used for isolation of the left or right lung of a patient for one lung ventilation. The VivaSight 2 DLT system is intended to be used for verifying tube placement and repositioning. Ambu VivaSight 2 DLT is intended for adult patients.
Indications for Use	Intubation with VivaSight 2 DLT is indicated for patients with pathological lung conditions or other medical conditions that require endobronchial intubation, mechanical ventilation and isolation of one lung from the other, e.g. for thoracic surgery.
Technological characteristics in comparison to the predicate device	Both Ambu VivaSight 2 DLT and the predicate device, ETView VivaSight-DL, are left-sided double-lumen endobronchial tubes with embedded video camera and light source. Both devices share similar technological characteristics such as tube size, effective inside diameters, outside bronchial diameters and tube length.

Both devices have flush lines with flush exits in front of the camera lens to enable cleaning of camera lens.

Both devices are connected to Ambu displaying units via an adapter cable.

The camera sensor resolution for Ambu VivaSight 2 DLT is higher than for ETView VivaSight-DL and the picture format slightly different.

Both devices have the same materials or substances in contact with the same human tissues or body fluids, except for small differences in the camera module and video connector.

Performance Testing - Bench

The following data have been submitted in the premarket notification to support safety and effectiveness of the device:

Declaration of conformity to the following applicable recognized consensus standards:

- ISO 16628:2008 Tracheobronchial tubes – Sizing and marking
- ISO 5356-1:2015 Anesthetic and respiratory equipment - Conical connectors – Part 1: Cones and sockets

Result: All tests passed.

Performance test reports to document the following properties:

- Product dimensions, incl. cuff diameters
- Effective inside diameter
- Tube connector dimensions
- Markings and color
- Kink and flow resistance
- Cuff leakage and herniation
- Cuffed tube collapse
- Leakage of lumens
- Mechanical resistance of junctions
- Duration of use
- Adapter cable connection to video connector
- Connect and power sequence
- Adapter cable connectors pull force
- Photobiological safety

Result: All tests passed.

Performance test reports to document shelf life. Tests were performed on finished, sterilized and aged products:

- Performance tests
- Sterile packaging integrity

Result: All tests passed.

Ambu VivaSight 2 DLT is classified as a breathing gas-pathway device and as a surface device having direct contact with mucosal membrane for limited duration in accordance with ISO 18562-1 and ISO 10993-1. Biocompatibility test reports to document compliance with the requirements of these standards:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Intracutaneous reactivity test (ISO 10993-10)
- Particulate matter emissions (ISO 18562-2)
- Volatile Organic Compound (VOC) emissions (ISO 18562-3)
- Leachable substances in condensate (ISO 18562-4)

Result: All tests passed.

Test reports that verify the Electromagnetic Compatibility and Electrical Safety:

- Electromagnetic Compatibility in compliance with IEC 60601-1-2
- Electrical Safety in compliance with IEC 60601-1 and IEC 60601-2-18

Result: All tests passed.

Conclusion

Ambu VivaSight 2 DLT and its accessory, Ambu VivaSight 2 Adapter Cable, have the same intended use, technological characteristics and principles of operation as the predicate device.

The minor technological differences between Ambu VivaSight 2 DLT and its predicate device raises no new questions regarding safety or effectiveness.

Performance testing has demonstrated that the device is as safe and effective as the predicate device.

Thus, Ambu VivaSight 2 DLT is substantially equivalent to its predicate device.