October 9, 2019

Securisyn Medical, LLC
Arthur Kanowitz
Founder, Chairman, Chief Medical Officer
9150 Commerce Center Circle, Suite 135
Highlands Ranch, Colorado 80129

Re: K190630
Trade/Device Name: SolidAIRity III Airway Stabilization System
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR, CBH
Dated: September 9, 2019
Received: September 10, 2019

Dear Arthur Kanowitz:

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/comboind-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.


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,

James J. Lee -S

for 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
510(k) Number (if known)
K190630

Device Name
SolidAIRity III Airway Stabilization System

Indications for Use (Describe)
The SolidAIRity III Endotracheal Standard Tube is indicated for airway management of patients requiring oral intubation.

The SolidAIRity III Endotracheal Suction Tube is indicated for airway management of patients requiring oral intubation and for evacuation and drainage of subglottic secretions that accumulate above the cuff.

The SolidAIRity III Endotracheal Tube Stabilizer is indicated for airway management of patients by securing a SolidAIRity III Endotracheal Tube during oral intubation.

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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Section 7: 510(k) Summary

Introduction:
This document contains the 510(k) Summary for the SolidAIRity® III Airway Stabilization System. The content of this summary is based on the requirements set forth in 21 CFR 807.92.

Applicant/Manufacturer Name and Address:
Securisyn Medical, LLC
9150 Commerce Center Circle, Suite 135
Highlands Ranch, CO USA 80129

510(k) Contact Person:
Arthur Kanowitz, MD FACEP
Founder, Chairman, Chief Medical Officer
Securisyn Medical, LLC

Email: akanowitz@securisyn.com
Tel: (720) 641-3540

Date Prepared:
March 8, 2019

Device Trade Name:
SolidAIRity® III Airway Stabilization System

Classification and Classification Name:
Name: Tube, Tracheal (W/Wo Connector)
Product Code: BTR
Regulation Number: 21 CFR 868.5730
Class: II
Panel: Anesthesiology

Predicate Devices:
BEVER Endotracheal Tube and BEVER Eva Endotracheal Tube (K111401, Primary Predicate)
Laerdal Thomas ET Tube Holder (K843790, Secondary Predicate)

Device Description:
The SolidAIRity III Airway Stabilization System consists of:

- Two (2) types of Oral Endotracheal Tubes (the SolidAIRity III Standard Oral Endotracheal Tube or the SolidAIRity III Suction Oral Endotracheal Tube), and
- The SolidAIRity III Endotracheal Tube Stabilizer
Each type (standard and suction) of the SolidAIRity III Oral Endotracheal Tubes will be available in the following five (5) adult sizes:

- 6.0mm ID
- 6.5mm ID
- 7.0mm ID
- 7.5mm ID
- 8.0mm ID

A clinician inserts the endotracheal tube into a patient’s trachea, via the mouth, in accordance with standard clinical technique to maintain an open airway. The stabilizer remains outside the patient’s mouth and, by means of a locking device and straps, secures the endotracheal tube in place.

**Standard Oral Endotracheal Tube Description**

The SolidAIRity III Standard Oral Endotracheal Tube is a sterile, single-use airway device designed to be used as part of the SolidAIRity III Airway Stabilization System. This oral endotracheal tube features a retention structure (KAD collar) that interfaces with the SolidAIRity III Stabilizer to secure the endotracheal tube. As a fully integrated stabilization system, the system is designed to resist movement of the tube against applied extubation forces of up to 20 pounds.

The tube design includes a pair of depth localizer bands that promote proper placement of the tracheal tube in relation to the patient’s vocal cords, as well as a depth indicator line on the KAD collar that allows for monitoring of tube depth relative to the Stabilizer tower and allows for easy and accurate depth repositioning of the ETT. The tube design also includes identification lettering ("ETT") on the inflation line to assist in preventing Luer fitting misconnections.

**Suction Oral Endotracheal Tube Description**

The SolidAIRity III Suction Oral Endotracheal Tube is identical to the SolidAIRity III Standard Oral Endotracheal Tube with an additional lumen for the suction functionality. The dorsal suction lumen allows suctioning of contaminated mucous or subglottic secretions that accumulate above the cuff. The tube design also includes identification lettering on both the inflation line ("ETT") and the suction line ("Suction") to assist in preventing Luer fitting misconnections.

**Stabilizer**

The SolidAIRity III Endotracheal Tube Stabilizer is a non-sterile, single-use endotracheal tube stabilization device designed to be used externally and only with the SolidAIRity III Standard or Suction Oral Endotracheal Tubes. This device uses a fixation mechanism to hold the SolidAIRity III Oral Endotracheal Tube firmly in place without crimping, pinching or squeezing the tube. Use of the SolidAIRity III Endotracheal Tube Stabilizer may withstand up to 20 pounds of external force.
Indications for Use Statement:
The SolidAIRity III Endotracheal Standard Tube is indicated for airway management of patients requiring oral intubation.

The SolidAIRity III Endotracheal Suction Tube is indicated for airway management of patients requiring oral intubation and for evacuation and drainage of subglottic secretions that accumulate above the cuff.

The SolidAIRity III Endotracheal Tube Stabilizer is indicated for airway management of patients by securing a SolidAIRity III Endotracheal Tube during oral intubation.

Technological Characteristics Comparison
The table below provides a comparison of the technological characteristics between the SolidAIRity III Airway Stabilization System and its identified predicate devices.

<table>
<thead>
<tr>
<th>Specification</th>
<th>SolidAIRity III Airway Stabilizer System (Endotracheal Tube and Stabilizer)</th>
<th>BEVER Endotracheal Tube and BEVER Eva Endotracheal Tube (Primary Predicate)</th>
<th>Laerdal Thomas ET Tube Holder (Secondary Predicate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(k) Number</td>
<td>TBD</td>
<td>K111401</td>
<td>K843790</td>
</tr>
<tr>
<td>Regulation Number</td>
<td>21 CFR 868.5730</td>
<td>21 CFR 868.5730</td>
<td>21 CFR 868.5770</td>
</tr>
<tr>
<td>Product Code</td>
<td>BTR</td>
<td>BTR</td>
<td>CBH</td>
</tr>
<tr>
<td>Classification</td>
<td>II</td>
<td>II</td>
<td>I</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>The SolidAIRity III Endotracheal Standard Tube is indicated for airway management of patients requiring oral intubation. The SolidAIRity III Endotracheal Suction Tube is indicated for airway management of patients requiring oral intubation and for evacuation and drainage of subglottic secretions that accumulate above the cuff. The SolidAIRity III Endotracheal Tube Stabilizer is indicated for airway management of patients by securing a SolidAIRity III Endotracheal Tube during oral intubation.</td>
<td>The BEVER™ Endotracheal tube is indicated for airway management by oral or nasal intubation of the trachea during mechanical ventilation and anesthesia. The BEVER EVA™ Endotracheal tube is indicated for airway management by oral intubation of the trachea and for evacuation or drainage of the contaminated mucous and subglottic secretion that accumulate above the cuff by continuous or intermittent suctioning.</td>
<td>Thomas Select Tube Holder is designed to secure advanced airway devices e.g. Endotracheal Tubes (ETs), Laryngeal Mask Airways (LMAs) and other wider Supraglottic Airway devices (SGAs), after insertion into the trachea or esophagus to reduce the risk of accidental extubation.</td>
</tr>
<tr>
<td>Intubation Route</td>
<td>Oral only</td>
<td>Oral or nasal</td>
<td>N/A</td>
</tr>
<tr>
<td>Patient Population</td>
<td>Adult</td>
<td>Pediatric and Adult</td>
<td>Pediatric and Adult</td>
</tr>
<tr>
<td>Intended Users</td>
<td>Physicians, respiratory therapists and paramedics</td>
<td>Physicians, respiratory therapists and paramedics</td>
<td>Physicians, respiratory therapists and paramedics</td>
</tr>
<tr>
<td>Use Environment</td>
<td>Hospital, Point of Use</td>
<td>Hospital, Point of Use</td>
<td>Hospital, Point of Use</td>
</tr>
<tr>
<td>Usage</td>
<td>Single Use</td>
<td>Single Use</td>
<td>Single Use</td>
</tr>
<tr>
<td>--------------</td>
<td>------------</td>
<td>------------</td>
<td>------------</td>
</tr>
<tr>
<td>Sterilization</td>
<td>ETT: Ethylene oxide Stabilizer: Non-sterile</td>
<td>Ethylene oxide</td>
<td>Non-sterile</td>
</tr>
<tr>
<td>ETT Outer Diameter Size Range (mm)</td>
<td>6.0 – 8.0mm in 0.5mm increments</td>
<td>BEVER: 4.0 – 10.0mm in 0.5mm increments BEVER Eva: 6.0 – 9.0mm in 0.5mm increments</td>
<td>N/A</td>
</tr>
<tr>
<td>Suction Mechanism</td>
<td>Yes</td>
<td>Yes</td>
<td>N/A</td>
</tr>
<tr>
<td>Suction Evacuation Port Location</td>
<td>Directly Proximal to Cuff</td>
<td>Directly Proximal to Cuff</td>
<td>N/A</td>
</tr>
<tr>
<td>Tube Design</td>
<td>Per ISO 5361</td>
<td>Per ISO 5361</td>
<td>N/A</td>
</tr>
<tr>
<td>Tube Material</td>
<td>Medical Grade PVC</td>
<td>Medical Grade PVC</td>
<td>N/A</td>
</tr>
<tr>
<td>Magill Curve</td>
<td>Per ISO 5361</td>
<td>Per ISO 5361</td>
<td>N/A</td>
</tr>
<tr>
<td>Murphy Eye</td>
<td>Per ISO 5361</td>
<td>Per ISO 5361</td>
<td>N/A</td>
</tr>
<tr>
<td>Radiopaque Stripe</td>
<td>Full length Barium Sulfite Radiopaque Line</td>
<td>Full length Barium Sulfite Radiopaque Line</td>
<td>N/A</td>
</tr>
<tr>
<td>Cuff Design</td>
<td>Barrel Shape; High Volume / Low Pressure</td>
<td>Barrel Shape; High Volume / Low Pressure</td>
<td>N/A</td>
</tr>
<tr>
<td>Cuff Inflation</td>
<td>Inflation tube with pilot balloon and self-sealing valve</td>
<td>Inflation tube with pilot balloon and self-sealing valve</td>
<td>N/A</td>
</tr>
<tr>
<td>Proximal (machine end) connection</td>
<td>SolidAIRity III 15mm connector with twist lock feature</td>
<td>Standard 15mm connector</td>
<td>N/A</td>
</tr>
<tr>
<td>Line Protection</td>
<td>Inflation Line / Suction Line Protection Hub</td>
<td>None</td>
<td>N/A</td>
</tr>
<tr>
<td>Depth Markers</td>
<td>Yes, numerical (cm): 6.0 ID = 17-22cm; 6.5 ID = 18-23cm; 7.0 ID = 19-24cm; 7.5 ID = 20-25cm; 8.0 ID = 21-26cm</td>
<td>Yes, numerical (cm): 18-28cm for all ID sizes</td>
<td>N/A</td>
</tr>
<tr>
<td>Location of Depth Markers</td>
<td>Printed on single side of tube</td>
<td>Printed on single side of tube</td>
<td>N/A</td>
</tr>
<tr>
<td>Depth Positioning Localizer Bands</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>ETT Securement Mechanism for Stabilizer</td>
<td>Ribbed KAD Collar to interface with SolidAIRity III Stabilizer</td>
<td>Compatible with common ETT stabilizers</td>
<td>Tube Clamp</td>
</tr>
<tr>
<td>Stabilizer/ETT Size Compatibility</td>
<td>6.0 – 8.0mm</td>
<td>N/A</td>
<td>4.3mm – 21.0mm</td>
</tr>
<tr>
<td>Stabilizer Openings for Oral Care</td>
<td>Yes</td>
<td>N/A</td>
<td>Yes</td>
</tr>
</tbody>
</table>
The Indications for Use of the SolidAIRity III Endotracheal Tubes and the primary predicate device are essentially the same. Both devices are indicated for airway management of patients requiring oral intubation. Although the primary predicate device is additionally indicated for nasal intubation, the indications of the subject device do not introduce new or different questions of safety and effectiveness since the scope of the subject device’s indications have been previously cleared by the Agency as part of a larger scope in the primary predicate device. The indications for use of the SolidAIRity III Endotracheal Tube Stabilizer and the secondary predicate device are essentially the same. Both devices are indicated for airway management of patients by securing an endotracheal tube. Although the secondary predicate device is additionally indicated for use with other endotracheal tubes, laryngeal mask airways, and other supraglottic airway devices, the subject device is only indicated for use with SolidAIRity III Endotracheal Tubes. These differences do not affect the intended use of the device for airway management of patients requiring oral intubation. The indications for use do not result in the subject device being used for a different patient population, by different users, or in different use environments. Therefore, the SolidAIRity III Airway Stabilization System can be determined to be substantially equivalent to the predicate devices in terms of indications for use.

The design of the SolidAIRity III Airway Stabilization System and the primary predicate device are substantially equivalent in that both designs are in accordance with ISO 5361. Both the SolidAIRity III Suction Oral Endotracheal Tubes and the BEVER Eva Endotracheal Tube (primary predicate device) are designed with an additional suction lumen for use during advanced airway management. The suction lumen allows for evacuation or drainage by suctioning of contaminated mucous or subglottic secretions that accumulate above the cuff. On both devices the suction evacuation port is located directly proximal to the cuff. The material from which both the subject device and the primary predicate tubes are manufactured are also identical. Additionally, both devices are disposable and intended for single-use. The SolidAIRity III Airway Stabilization System is designed with features such as the inflation line / suction line protection hub, KAD collar, and Stabilizer. Although the primary predicate device does not offer these additional means of risk mitigation, the performance testing demonstrates that these features do not affect safety and effectiveness of the subject device. Many of the technological characteristics between the SolidAIRity III Airway Stabilization System and the predicate devices are essentially identical. Any differences are either minor or have been supported by risk mitigation and performance test data.
Summary of Testing

Biocompatibility testing was performed in accordance to FDA Guidance “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process’”. The results of the testing satisfy the requirements of the study protocols and comply with ISO 10993-1. The battery of testing included the following tests:

<table>
<thead>
<tr>
<th>Test</th>
<th>Standard</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytotoxicity</td>
<td>ISO 10993-5</td>
<td>Pass</td>
</tr>
<tr>
<td>Sensitization</td>
<td>ISO 10993-10</td>
<td>Pass</td>
</tr>
<tr>
<td>Irritation</td>
<td>ISO 10993-10</td>
<td>Pass</td>
</tr>
<tr>
<td>Acute Systemic Toxicity</td>
<td>ISO 10993-11</td>
<td>Pass</td>
</tr>
<tr>
<td>Material-Mediated Pyrogenicity</td>
<td>ISO 10993-11</td>
<td>Pass</td>
</tr>
<tr>
<td>Subacute / Subchronic Toxicity</td>
<td>ISO 10993-11</td>
<td>Pass</td>
</tr>
<tr>
<td>Genotoxicity</td>
<td>ISO 10993-3</td>
<td>Pass</td>
</tr>
<tr>
<td>Implantation</td>
<td>ISO 10993-6</td>
<td>Pass</td>
</tr>
</tbody>
</table>

The device is sterilized by ethylene oxide. The sterilization process is validated to comply with ISO 11135-1 and ISO 10993-7. A formal package validation has been conducted in accordance with ISO 11607-1 on non-aged and aged product following 2-year accelerated aging in accordance with ASTM 1980 to demonstrate that the device and packaging integrity remain in compliance with the specifications throughout transport, storage, and shelf-life. The results of all testing met acceptance criteria.

A Human Factors Validation Study was conducted in accordance with FDA Guidance “Applying Human Factors and Usability Engineering to Medical Devices”. Usability of the SolidAIRity III Airway Stabilization System was evaluated in simulated use scenarios employing accepted models of evaluation. The scenario-based simulated use human factors validation was performed in simulated environments consistent with those environments in which representative users typically perform airway management. The Human Factors Validation data demonstrate that users can perform all phases of advanced airway management (pre-intubation preparation, intubation, stabilization, routine care, and extubation) as safely and as effectively as the predicate with the SolidAIRity III Airway Stabilization System for the intended users, uses, and use environments.

Performance bench testing was conducted on the SolidAIRity III Airway Stabilization System. The following tests were performed in accordance with ISO 5361:

- Endotracheal Tube Conformance Test
- Cuff Inflation Tube Leak Test
- Cuff Resting Diameter Test
- Cuffed Tube Collapse Test
- Cuff Herniation Test
• Tracheal Seal Test
• Kink Resistance Test
• Radiopaque Marker Compliance Test

Additional performance bench testing was conducted on the KAD collar and inflation tube to ensure proper performance strength of assembly with respect to external forces. A comparative inflation tube pull test was performed on the SolidAIRity III Endotracheal Tube and Mallinckrodt Hi-Lo Evac Endotracheal Tube to further support substantial equivalence. Suction tube performance testing was conducted on the subject and predicate device in accordance with ISO 8836 to provide objective evidence that the performance of the SolidAIRity III Suction Endotracheal Tube is substantially equivalent to that of the predicate device. Resistance to Movement Against Force testing was conducted to validate the ability of the SolidAIRity III Airway Stabilization System to resist tube movement against multidirectional external forces of up to 20 pounds under simulated use. The results of all performance bench testing met the pre-defined acceptance criteria.

Clinical testing was not conducted as part of the submission.

Conclusion
The SolidAIRity III Airway Stabilization System is substantially equivalent to legally marketed predicate devices with respect to intended use/indications for use, target user, patient population, use environment and technological characteristics.