DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 24, 2015

Covidien
Brianna Reynolds
Regulatory Affairs Specialist
6135 Gunbarrel Avenue
Boulder, CO 80301

Re: K142296
Trade/Device Name: Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Disposable Inner Cannula;
Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Disposable Inner Cannula
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: JOH
Dated: January 22, 2015
Received: January 23, 2015

Dear Ms. Reynolds,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K142296

Device Name:

Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Disposable Inner Cannula

Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Disposable Inner Cannula

Indications for Use:

- Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Disposable Inner Cannula is intended for use in providing tracheal access for airway management.
- Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Disposable Inner Cannula is intended for use in providing tracheal access for airway management.
- Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Disposable Inner Cannula is also intended for use with Cook® Percutaneous Dilatational Tracheotomy (PDT) procedures.
- The Shiley™ Disposable Inner Cannula is intended to be used with the appropriate Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff or Cuffless to provide tracheal access for airway management.

Prescription Use ____X_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

COVIDIEN

510(k) Summary

Date summary prepared 23 February 2015

510(k) Submitter/Holder

Covidien llc
6135 Gunbarrel Avenue
Boulder, CO 80301

Contact

Danielle Mueller
Regulatory Affairs Manager
Phone: 303-305-2603
Fax: 303-305-2212

Name of Device

Trade Name:	Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Disposable Inner Cannula Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard Cuff, Disposable Inner Cannula
Catalog Numbers:	xUNxx and xCNxx
Common Name:	Tube Tracheostomy and Tube Cuff
Classification Name:	JOH, Tube Tracheostomy and Tube Cuff (21 CFR 868.5800) Class II, 73-Anesthesiology

Purpose of Submission

The purpose of this submission is to introduce the Covidien Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Disposable Inner Cannula and Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard Cuff, Disposable Inner Cannula. The subject and predicate device have the equivalent indications for use, intended use, fundamental technology, and design. This submission is to notify the FDA of the following changes:

- Updated the materials used in the Tracheostomy tubes to a Medical Grade PVC with a citrate and DEHT based plasticizer
- Addition of the Covidien taper-shaped cuff referred to as TaperGuard
- Tapered tracheostomy tube tip compatible with percutaneous insertion
- Line extension to include 3 intermediate sizes for cuffed and cuffless
- Integrated ISO compliant 15 mm connector
- Flexible molded flange

Predicate Device

The Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Disposable Inner Cannula and the Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard Cuff, Disposable Inner Cannula were compared and found to be substantially equivalent to the following products of comparable type in commercial distribution:

Trade Name:	Shiley™ Tracheostomy Tubes
Device Common Name:	Tube Tracheostomy and Tube Cuff
510(k) Number:	K962173
Manufacturer:	Covidien, formerly Tyco Healthcare

Trade Name:	Shiley™ DCT Adult Cuffed Percutaneous Tracheostomy Tubes
Device Common Name:	Tube Tracheostomy and Tube Cuff
510(k) Number:	K963732
Manufacturer:	Covidien, formerly Tyco Healthcare

Intended Use

The device is intended to be used to provide an artificial airway in order to provide access to the patient's airway for airway management. When inserted in a tracheotomy stoma, the device is secured in place with a neck strap around the patient's neck which is attached to an integral neck plate, thereby providing for a secure artificial airway for spontaneous breathing or direct hook-up to ventilation or anesthesia equipment.

Indications for Use

- Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Disposable Inner Cannula is intended for use in providing tracheal access for airway management.
- Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Disposable Inner Cannula is intended for use in providing tracheal access for airway management.
- Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Disposable Inner Cannula is also intended for use with Cook® Percutaneous Dilatational Tracheotomy (PDT) procedures.
- The Shiley™ Disposable Inner Cannula is intended to be used with the appropriate Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff or Cuffless to provide tracheal access for airway management.

Device Description

The Shiley™ Adult Flexible Tracheostomy Tube Cuffless is a dual cannula tracheostomy tube with a disposable inner cannula. The device is used to provide an artificial airway in order to provide access to the patient's airway for airway management. It contains an integrated 15 mm connector for use with standard ventilation and anesthesia equipment. The tracheostomy tube has a radiopaque outer cannula constructed of polyvinyl chloride. A pliable neck plate allows conformity to individual neck anatomies and contains two suture holes. The tapered tracheostomy tube tip is compatible with percutaneous insertion. The smooth, rounded tip obturator facilitates insertion. The disposable inner cannula is translucent for easy inspection and allows for airway maintenance. This tracheostomy tube can be used with or without the disposable inner cannula included in the package however, use of the inner cannula is recommended.

The Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff is a dual cannula tracheostomy tube with a disposable inner cannula. The device is used to provide an artificial airway in order to provide access to the patient's airway for airway management. It contains an integrated 15 mm connector for use with standard ventilation and anesthesia equipment. The Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff has a radiopaque outer cannula constructed of polyvinyl chloride. A pliable neck plate allows conformity to individual neck anatomies and contains two suture holes. The tapered tracheostomy tube tip is compatible with percutaneous insertion. The smooth, rounded tip obturator facilitates insertion. The disposable inner cannula is translucent for easy inspection and allows for airway maintenance. The tracheostomy tube has a taper-shaped, low-pressure cuff to provide an effective air and fluid seal and minimize tracheal wall damage. The cuff inflation line has a luer valve with an integral pilot balloon. The Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff can be used with or without the disposable inner cannula included in the package however, use of the inner cannula is recommended.

When inserted in a tracheotomy stoma, the device may be secured in place with a neck strap around the patient's neck which is attached to an integral neck plate. It also may be secured in place by using the suture holes in the flange of the tracheostomy tube, thereby providing for a secure artificial airway for spontaneous breathing or direct connection to ventilation or anesthesia equipment.

	Subject Device:	Predicate Device	Predicate Device
	Shiley ™ Adult Flexible Tracheostomy Tube Cuffless, Disposable Inner Cannula and Shiley ™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Disposable Inner Cannula	Shiley ™ Tracheostomy Tubes (K962173) (Cuffless and Cuffed)	Shiley ™ DCT Adult Cuffed Percutaneous Tracheostomy Tubes (K963732)
Indications for Use	Shiley ™ Adult Flexible Tracheostomy Tube Cuffless, Disposable Inner Cannula is intended for use in providing tracheal access for airway management. Shiley ™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Disposable Inner Cannula is intended for use in providing tracheal access for airway management. The Shiley ™ Disposable Inner Cannula is intended to be used with the appropriate Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff or Cuffless to provide tracheal access for airway management. Shiley ™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Disposable Inner Cannula is also intended for use with Cook® Percutaneous Dilatational Tracheotomy (PDT) procedures.	This device is intended for use in providing tracheal access for airway management.	This device is intended for use in providing tracheal access for airway management. The device is primarily intended for use in conjunction with Percutaneous Dilatational Tracheostomy and is inserted into the patient using the introducer provided with the Percutaneous kit.
Intended Use	The device is intended to be used to provide and artificial airway in order to provide access to the patient's airway for airway management. When inserted in a tracheotomy stoma, the device is secured in place with a neck strap around the patient's neck which is attached to an integral neck plate, thereby providing for a secure artificial airway for spontaneous breathing or direct hook-up to ventilation or anesthesia equipment.	The device is intended to be used to provide and artificial airway in order to provide access to the patient's airway for airway management. When inserted in a tracheotomy stoma, the device is secured in place with a neck strap around the patient's neck which is attached to an integral neck plate, thereby providing for a secure artificial airway for spontaneous breathing or direct hook-up to ventilation or anesthesia equipment	The device is intended to be used to provide and artificial airway in order to provide access to the patient's airway for airway management. When inserted in a tracheotomy stoma, the device is secured in place with a neck strap around the patient's neck which is attached to an integral neck plate, thereby providing for a secure artificial airway for spontaneous breathing or direct hook-up to ventilation or anesthesia equipment
Device class	Class 2	Class 2	Class 2
Product code	JOH	JOH	JOH
Patient Population	Adult patients requiring an artificial airway	Adult patients requiring an artificial airway	Adult patients requiring an artificial airway
Environment of Use	The product shall be used in a clinical environment such as critical care units of a hospital, non-critical care units of a hospital, long term care facilities and home care.	The product shall be used in a clinical environment such as critical care units of a hospital, non-critical care units of a hospital, long term care facilities and home care.	The product shall be used in a clinical environment such as critical care units of a hospital, non-critical care units of a hospital, long term care facilities and home care.
Invasive / Non-Invasive	Invasive	Invasive	Invasive
Sterilization	Sterile: The SAL is 10E-6 utilizing the existing equivalent validated cycle 2.	Sterile: The SAL is 10E-6 utilizing the existing validated cycle 66.	Sterile: The SAL is 10E-6 utilizing the existing validated cycle 66.
Shelf Life	2-year shelf life	5-year shelf life	5-year shelf life
Materials			
Cannula	Medical Grade PVC with a citrate Based plasticizer	Medical Grade PVC	Medical Grade PVC
Neck Plate	Medical Grade PVC with a citrate based plasticizer	Medical Grade PVC	Medical Grade PVC
15 MM connector	Polymethylpentene - TPX	Medical Grade PVC	Medical Grade PVC
Cuff if applicable by product type	Medical Grade PVC with a DEHT based plasticizer	Medical Grade PVC	Medical Grade PVC
Inflation System	Medical Grade PVC with a citrate based plasticizer	Medical Grade PVC and Acrylonitrile butadiene styrene (ABS)	Medical Grade PVC and Acrylonitrile butadiene styrene (ABS)
Obturator	Medical Grade Polypropylene	Medical Grade Polypropylene	Medical Grade Polypropylene
Tie Strap	Cotton	Cotton	Cotton
Biocompatibility	ISO 10993-1:2009	ISO 10993-1:2009	ISO 10993-1:2009

<table>
<tr><th></th><th>Subject Device:</th><th>Predicate Device</th><th>Predicate Device</th></tr>
<tr><td></td><td>Shiley ™ Adult Flexible Tracheostomy Tube Cuffless, Disposable Inner Cannula and Shiley ™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, Disposable Inner Cannula</td><td>Shiley ™ Tracheostomy Tubes (K962173) (Cuffless and Cuffed)</td><td>Shiley ™ DCT Adult Cuffed Percutaneous Tracheostomy Tubes (K963732)</td></tr>
<tr><td>Sizes</td><td>Cuffless:
<table><tr><th>REF</th><th>ID (mm)</th><th>OD (mm)</th><th>Length (mm)</th></tr><tr><td>4UN65A</td><td>6.5</td><td>9.4</td><td>62</td></tr><tr><td>5UN70A</td><td>7.0</td><td>10.1</td><td>68</td></tr><tr><td>6UN75A</td><td>7.5</td><td>10.8</td><td>74</td></tr><tr><td>7UN80A</td><td>8.0</td><td>11.4</td><td>77</td></tr><tr><td>8UN85A</td><td>8.5</td><td>12.2</td><td>79</td></tr><tr><td>9UN90A</td><td>9.0</td><td>12.7</td><td>79</td></tr><tr><td>10UN10A</td><td>10.0</td><td>13.8</td><td>79</td></tr></table>
Cuffed:
<table><tr><th>REF</th><th>ID (mm)</th><th>OD (mm)</th><th>Length (mm)</th><th>Flange</th></tr><tr><td>4CN65A</td><td>6.5</td><td>9.4</td><td>62</td><td>20.6</td></tr><tr><td>5CN70A</td><td>7.0</td><td>10.1</td><td>68</td><td>25.4</td></tr><tr><td>6CN75A</td><td>7.5</td><td>10.8</td><td>74</td><td>25.4</td></tr><tr><td>7CN80A</td><td>8.0</td><td>11.4</td><td>77</td><td>25.4</td></tr><tr><td>8CN85A</td><td>8.5</td><td>12.2</td><td>79</td><td>28.6</td></tr><tr><td>9CN90A</td><td>9.0</td><td>12.7</td><td>79</td><td>28.6</td></tr><tr><td>10CN10A</td><td>10.0</td><td>13.8</td><td>79</td><td>28.6</td></tr></table></td><td>Cuffless:
<table><tr><th>REF</th><th>ID (mm)</th><th>OD (mm)</th><th>Length (mm)</th></tr><tr><td>4DCT</td><td>5.0</td><td>9.4</td><td>62</td></tr><tr><td>6DCT</td><td>6.4</td><td>10.38</td><td>74</td></tr><tr><td>8DCT</td><td>7.6</td><td>12.2</td><td>79</td></tr><tr><td>10DCT</td><td>8.9</td><td>13.8</td><td>79</td></tr></table>
Cuffed:
<table><tr><th>REF</th><th>ID (mm)</th><th>OD (mm)</th><th>Length (mm)</th><th>Flange</th></tr><tr><td>4DCFS</td><td>5.0</td><td>9.4</td><td>62</td><td>20</td></tr><tr><td>6DCFS</td><td>6.4</td><td>10.38</td><td>74</td><td>24</td></tr><tr><td>8DCFS</td><td>7.6</td><td>12.2</td><td>79</td><td>27</td></tr><tr><td>10DCFS</td><td>8.9</td><td>13.8</td><td>79</td><td>29</td></tr></table></td><td><table><tr><th>REF</th><th>ID (mm)</th><th>OD (mm)</th><th>Length (mm)</th><th>Flange</th></tr><tr><td>6PERC</td><td>6.4</td><td>10.8</td><td>74</td><td>24.1</td></tr><tr><td>8PERC</td><td>7.6</td><td>12.2</td><td>79</td><td>27.2</td></tr></table></td></tr>
<tr><td>Percutaneous Compatible Size</td><td>Cuffed:
-4CN65
-5CN70
-6CN75
-7CN80
-8CN85

Cuffless:
-4UN65
-5UN70
-6UN75
-7UN80
-8UN85</td><td>NA</td><td>6 PERC
8 PERC</td></tr>
<tr><td>Use</td><td>Single Patient Use</td><td>Single Patient Use</td><td>Single Patient Use</td></tr>
<tr><td>Design</td><td>Tracheostomy Tube Design</td><td>Tracheostomy Tube Design</td><td>Tracheostomy Tube Design</td></tr>
<tr><td>Standards met</td><td>ISO 5366-1:2009 Anesthetic and Respiratory Equipment -- Tracheostomy Tubes -- Part 1: Adult Tracheostomy Tubes

ISO 5356-1:2004 Anesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets

ISO 5361: 2012
Anesthetic and respiratory equipment—Tracheal tubes and connectors</td><td>5356 (1987)
5366 (1985)</td><td>5356 (1987)
5366 (1985)</td></tr>
</table>

Technological Characteristics

The Covidien Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Disposable Inner Cannula and the Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard Cuff, Disposable Inner Cannula have technological characteristics that differ from its predicates.

The materials used in the Covidien Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Disposable Inner Cannula and the Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard Cuff, Disposable Inner Cannula have been updated to a Medical Grade PVC with a Citrate and DEHT plasticizer. The subject device includes the addition of the Covidien taper-shaped cuff referred to as TaperGuard. A flexible molded flange with an integrated 15mm connector was designed into the tracheostomy tube. A one piece disposable inner cannula was designed to facilitate use of the tracheostomy tube both with and without the inner cannula in place. Finally, a product line extension has been added to include 3 intermediate sizes of cuffed and cuffless product. All other fundamental technological characteristics are identical to the predicate devices.

Non-Clinical Data

The following types of non-clinical testing were performed to establish substantial equivalence to the predicates:

- ISO 5356-1:2004
- ISO 5366-1:2009
- ISO 5361:2012
- Biocompatibility:
    - Cytotoxicity
    - Sensitization
    - Irritation
    - Acute systemic toxicity
    - Genotoxicity
    - Subchronic toxicity implantation
    - Chemical characterization
    - Risk assessment
- Performance testing:
    - Cuff pressure mapping
    - Flange tape tie
    - Air leak
    - Inflation line pull tests
    - Cuff puncture & air seal tests
    - Insertion/removal tests
    - Percutaneous compatibility

The results of these non-clinical tests show that the subject device can be considered substantially equivalent to the legally marketed predicate and no new questions of safety and efficacy have been raised.

Clinical Data

Not required to show substantial equivalence.

Substantial Equivalence

The Covidien Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Disposable Inner Cannula and the Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard Cuff, Disposable Inner Cannula have the same fundamental technology and design of the predicate Shiley™ Tracheostomy Tubes (K962173) and the Shiley™ DCT Adult Cuffed Percutaneous Tracheostomy Tubes (K963732). The materials on the tracheostomy tube have been updated to include a medical grade PVC with citrate and DEHT based plasticizer. A tapered tracheostomy tube tip is compatible with percutaneous insertion has been included. The subject device also includes the addition of the Covidien taper-shaped cuff referred to as TaperGuard.

The changes in the Covidien Shiley™ Adult Flexible Tracheostomy Tube Cuffless, Disposable Inner Cannula and the Shiley™ Tracheostomy Tube with TaperGuard Cuff, Disposable Inner Cannula do not impact the safety or effectiveness of the finished device.

Conclusion

Substantial equivalence of the subject device is shown through performance testing, as stated above. The subject and predicate devices have similar indications, size range, intended use, environment of use, and patient population. The subject and predicate devices differ in number of sizes available, taper shape, materials and enhanced basic design. No new questions of safety and effectiveness have been raised. From the evidence presented in the Premarket Notification, the subject device can be considered substantially equivalent.