# 510(k) SUMMARY K182861

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a 510(k) Summary for the Shiley™ Neonatal/Pediatric Tracheostomy Tube.

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| **Date:** | February 19, 2019 |
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| **Proprietary Name:** | Shiley™ Neonatal/Pediatric Tracheostomy Tube |
| **Common Name:** | Tracheostomy Tube & Tube Cuff |
| **Device Classification Regulation:** | 21 CFR 868.5800 – Class II |
| **Device Product Code & Panel:** | JOH |
| **Predicate Devices:** | Shiley™ Neonatal/Pediatric Tracheostomy Tube Cuffless (K122531)<br>Shiley™ Neonatal/Pediatric Tracheostomy Tube with TaperGuard™ Cuff (K142298) |
| **Reference Device:** | Shiley™ Neonatal/Pediatric long Tracheostomy Tube (K945513)<br>Shiley™ cuffed Pediatric long Tracheostomy Tube (K955680) |

**Device Description**
The subject devices are single patient use tracheostomy tubes that are intended to provide an artificial airway for airway management. It is available in multiple neonatal and pediatric sizes, all of which are available either cuffless or with a TaperGuard™ cuff. The products have a radiopaque tube with a clear flange and standard 15mm connector for direct connection to standard ventilation and anesthesia equipment. The products are not made with natural rubber latex or DEHP.

**Indications for Use/Intended Use**
The device is intended for use in providing tracheal access for airway management.

**Technological Characteristics Comparison**
The subject device is identical in intended use, basic design, functionality, and size range to the predicate devices. The subject device features a few design and material changes compared to the predicates. The

cannula angle of the subject device features a more narrowed angle range in comparison to the predicate device. The subject device features a one-piece flange with integrated 15mm connector; whereas, the predicate featured a two-piece design. The materials of the subject device cannula, 15mm connector and flange, and cuff were changed to a different grade of non-DEHP PVC in comparison to the predicate device. A comparison table is provided below.

| | | SUBJECT | PREDICATE | |
|---|---|---|---|---|
| | | **Shiley™ Neonatal/Pediatric Tracheostomy Tube (cuffed & cuffless)** | **Shiley™ Neonatal/Pediatric Tracheostomy Tube – cuffed [K142298]** | **Shiley™ Neonatal/Pediatric Tracheostomy Tube – cuffless [K122531]** |
| **Intended Use** | | Providing tracheal access for airway management | Identical | Identical |
| **Patient Population** | | Neonatal & pediatric | Identical | Identical |
| **Environment of Use** | | Hospitals, long-term care facilities, home care | Identical | Identical |
| **Use** | | Single patient | Identical | Identical |
| **Sterilization** | | Ethylene oxide | Identical | Identical |
| **Shelf Life** | | 5 years | Identical | Identical |
| **MR Compatibility** | | MR Conditional (cuffed); MR Safe (cuffless) | Not specified | Not specified |
| **DESIGN** | | | | |
| **Device Design** | | Per ISO 5366-1, ISO 5366-3, ISO 5356-1 | Per ISO 5366-1, ISO 5366-3, ISO 5356-1 | Per ISO 5366-1, ISO 5366-3, ISO 5356-1 |
| **Size Range** | **Neonatal** | 2.5 – 4.5 | Identical | Identical |
| | **Pediatric** | 2.5 – 6.5 | Identical | Identical |
| **Flange** | | Transparent flexible material with integrated connector | Transparent flexible material; 2-piece design | Transparent flexible material; 2-piece design |
| **Connector** | | Flexible, integrated with flange (1-piece design) | Rigid 15mm cap molded to flange (2-piece design) | Rigid 15mm cap molded to flange (2-piece design) |
| **Cannula Angle** | | 120° (105-120°) | 120° | 120° |
| **Cannula Wall** | **Cuffed** | Lumen present | Identical | N/A |
| | **Cuffless** | No lumen | N/A | Lumen present |
| **Radiopaque Cannula** | | Yes | Yes | Yes |
| **Cuff** | | Taper-shaped, low-pressure | Identical | N/A |
| **Inflation System** | | Inflation line, pilot balloon, inflation valve, luer guard | Identical | N/A |
| **Obturator & Neck Strap** | | Identical to predicate | Identical | Identical |
| **MATERIALS** | | | | |
| **Cannula** | | Non-DEHP PVC | Non-DEHP PVC | Non-DEHP PVC |
| **Flange** | | Non-DEHP PVC | Non-DEHP PVC | Non-DEHP PVC |
| **15mm Connector** | | Non-DEHP PVC | ABS | ABS |
| **Cuff** | | Non-DEHP PVC | Non-DEHP PVC | N/A |
| **Inflation System** | **Inflation line** | Non-DEHP PVC | Identical | N/A |
| | **Pilot balloon** | Non-DEHP PVC | Identical | |

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|---|---|---|---|---|
| | **Inflation valve** | PVC housing with metal spring and nitrile gasket | Identical | |
| | **Luer guard** | Non-DEHP PVC | Identical | |
| **Obturator** | | Polypropylene | Identical | Identical |
| **Neck Strap** | | Cotton | Identical | Identical |

**Substantial Equivalence – Summary of Performance Testing**

The following performance data were provided in support of the substantial equivalence determination:

**Biocompatibility testing**
The biocompatibility evaluation was conducted in accordance with FDA Guidance "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.
The tests included are cytotoxicity, sensitization, irritation, acute systemic toxicity, genotoxicity, subchronic toxicity, material mediated rabbit pyrogen, implantation, chemical characterization, and risk assessment.

**Sterilization and Packaging Validation**
Validation was conducted to ensure the subject device product sterility to the end user for ISO 11135-1 and ISO 10993-7 is acceptable. Packaging validation was in accordance with ISO 11607-1.

**MRI Compatibility**
MRI safety and compatibility and MR compatibility labeling for the subject devices in accordance with FDA guidance "Establishing Safety and Compatibility of Passive Implants in the MR Environment", and ASTM F2503-13.

**Bench Testing**
Bench testing on the subject device was conducted in accordance with ISO 5366-1, ISO 5366-3, ISO 5356-1. In addition, internal bench testing to assess the cuff performance, connector mechanical performance and cannula bend were performed.

**Substantial Equivalence – Clinical Evidence**
N/A – Clinical evidence was not necessary to show substantial equivalence.

**Substantial Equivalence – Conclusions**
No new questions of safety and effectiveness have been raised. From the evidence presented in the Premarket Notification, the subject devices can be considered substantially equivalent.