

K962123

OCT 4 1996

Appendix E  
Page 1 of 3**510(k) Class II SUMMARY****Date Submitted:** May 31, 1996**Submitter:** Mallinckrodt Medical, Inc.  
Establishment Registration Number 2029387,  
18691 Jamboree Road  
Irvine, CA 92715**Contact Person:** Michael Schoeck, Regulatory Affairs Associate  
Mallinckrodt Medical, Inc.  
675 McDonnell Blvd.  
Hazelwood, MO 63134 (corporate offices)  
(314) 895-2318 (phone) or (314) 895-2355 (fax)**Device Name:** Shiley Tracheostomy Tubes**Common Name and Classification:** Tracheostomy Tube and tube cuff, 21 CFR 868.5800**Predicate Devices:**

<b>Predicate Device Name</b>	<b>Product Designation</b>	<b>510(k) Number</b>
1. Shiley Low Pressure, Cuffed Tracheostomy Tube	LPC	K792222, 12/18/79 K811033, 5/13/81
2. Shiley Fenestrated, Low Pressure, Cuffed Tracheostomy Tube	FEN	K812302, 9/8/81
3. Shiley Cuffless Tracheostomy Tubes	CFS (non-fenestrated) CFN (fenestrated)	pre-amendment
4. Shiley Laryngectomy Tube	LGT	K821993, 8/12/82
5. Shiley Disposable Cannula, Low Pressure, Cuffed Tracheostomy Tube	DCT	K811447, 6/26/81
6. Shiley Disposable Cannula, Fenestrated, Low Pressure, Cuffed Tracheostomy Tube	DFEN	K843729, 10/19/84 K865061, 1/15/87
7. Shiley Disposable Cannula, Cuffless Tracheostomy Tubes	DCFS (non-fenestrated) DCFN (fenestrated)	K880614, 3/9/88
8. Shiley Pediatric/Neonatal Tracheal Tubes	PED NEO	K945513, 1/13/95
9. Shiley Single Cannula Tracheostomy Tube	SCT	K810106, 2/2/81

**Device Description:**

These devices are used to provide an artificial airway, in order to assist in the treatment of a variety of respiratory diseases and airway management in adults. After insertion in place through a tracheotomy incision in the patient's neck and trachea, the devices are then secured in place with a tiestrap around the patient's neck, which is attached to the tracheostomy tube's swivel neck plate/flange. Once in place, these devices provide a secure artificial airway for spontaneous breathing or direct hook-up to ventilation or anesthesia equipment.

Each device described in this present notification will be essentially *identical* to an existing Shiley Tracheostomy Tube. The *only* modification to each of these nine marketed devices will be replacement of the current *stiff* swivel neck plate/flange with a *soft*, contoured swivel neck plate/flange to facilitate conformity to individual neck anatomies and, thus, improve patient comfort.

<b>Products Which will Incorporate the new Soft Swivel Neck Plate/flange</b>	<b>Product Designation)</b>
1. Shiley Low Pressure, Cuffed Tracheostomy Tube	LPC
2. Shiley Fenestrated, Low Pressure, Cuffed Tracheostomy Tube	FEN
3. Shiley Cuffless Tracheostomy Tube (non-fenestrated)	CFS
4. Shiley Cuffless Tracheostomy Tube (fenestrated)	CFN
5. Shiley Laryngectomy Tube	LGT
6. Shiley Disposable Cannula, Low Pressure, Cuffed Tracheostomy Tube	DCT
7. Shiley Disposable Cannula, Fenestrated, Low Pressure, Cuffed Tracheostomy Tube	DFEN
8. Shiley Disposable Cannula, Cuffless Tracheostomy Tube (non-fenestrated)	DCFS
9. Shiley Disposable Cannula, Cuffless Tracheostomy Tube (fenestrated)	DCFN

**Intended Use:** The intended use of the modified devices will continue to be provision of tracheal access for airway management in adults.

**Comparison of Technological Characteristics of Subject Versus Predicate Devices:**

**Similarities:**

- The modified tracheostomy tubes will be *identical* to their respective predicate devices in intended use, indications for use, ID, OD, length, # of fenestrations, location and size of fenestrations, cannula bend, and in their packaged accessories.
- The modified trach tubes will feature a soft (not rigid) neck plate design like the predicate PED/NEO and SCT devices.
- All materials used in the modified tracheostomy tubes and their packaged accessories will *remain the same* as the predicate devices. *Only* the configuration and materials of the swivel neck plate/flange on each device will change.
- The product designations (i.e., model #'s) for each of the modified Trach Tubes will **remain the same**.

- Since the soft swivel neck plate/flange is used clinically in the same way as the previous rigid swivel neck plate/flange, it will be *unnecessary to modify the Instructions for Use*.

**Differences:**

- The swivel neck plate/flanges have changed from a uniformly rigid polycarbonate design to a configuration which combines *both* rigid and soft biocompatible plastic materials.

The new neck plate/flange will feature a rigid copolyester core for strength. The pins upon which the neck plate/flange swivels (after connection to the main body of the Trach tube) are part of this rigid inner core.

Soft PVC will then be *overmolded* around the rigid core to form the outer surface of the swivel neck plate/flange. Thus, the outer surface of the neck plate will be soft and flexible along the edges.

- The soft swivel neck plate/flange will also be slightly larger and more contoured than the current design to facilitate patient comfort.

**Performance/Clinical Data:**

**A. In-vitro performance data:**

Test	Predicate Device Test Results	Modified Device Test Results	CEN Standard Requirements
Tie Strap Hole Strength:	26.7 lbs force (SCT)	32.1 lbs force	No requirement for this test parameter
Neck Plate to Trach Tube Body Attachment Strength:	42.1 lbs force (DCT)	22.7 lbs force	minimum 11.3 lbs force

**B. Clinical Data:** Clinical data was not necessary, since device performance can be adequately assessed by in-vitro testing.

In conclusion, the similarities to the predicate devices, in conjunction with the physical integrity test results, demonstrate that the soft swivel neck plate/flange modification to these devices does not impact safety or effectiveness.

**Summary:**

The data presented demonstrate that the proposed modification (soft swivel neck plate/flange) to Shiley Tracheostomy Tubes does not impact device performance characteristics and, thus, does not raise new safety and efficacy questions. This information supports the conclusion that the modified Shiley Tracheostomy Tubes and accessories are substantially equivalent in intended use, operation, and characteristics, as compared to existing legally marketed devices.