

K955645



NON-CONFIDENTIAL SUMMARY OF SAFETY AND EFFECTIVENESS

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Proprietary or Trade Name: CATH-GUIDE

Common/Usual Name: Suction catheter, tracheobronchial

Intended Device: CATH-GUIDE

Predicate Devices:

Ballard Medical Products, Inc.	Trach Care Catheter	k872621
Concord/Portex	Steri-cath	k902383
	Steri-cath double lumen	k902687
	Maxi-Flo Suction Catheter	preamendment
Davol	Sleeved suction catheter only	preamendment
Dryden Corporation	Vent-02-Cath	k760371

Device Description:

Hudson RCI intends to introduce a full range of suction catheters and configurations. In summary these are:

1. Suction catheters only
2. Suction catheter with a protective sleeve only
3. Continuous ventilating suction catheter system with patient connector and irrigation port

Each product incorporates the same suction catheter tubing and suction control valve. The differences are whether the device has -

* protective sleeve for catheter



**Non-Confidential Summary of Safety and Effectiveness
(continued)**

Device description: (continued)

- * Incorporates a patient connector for direct attachment to the patient airway connector and ventilator circuit
- * Patient connector is a "Tee" or an "Angled" configuration which may also incorporate a swivel feature

Intended use:

Indicated use - Patients requiring suctioning of airway secretions

Targeted population - Neonates to adults

Environment of use - Where removal of airway secretions is performed, generally, hospital, ICU settings, facilities with mechanical ventilator care, ER and EMS

Comparison to predicate devices:

Attribute	Continuous Ventilating Systems			Standard Catheter Only		
	Hudson RCI Soft Tech	Ballard Trach Care	Concord-Portex Steri-cath	Hudson RCI Catheter & sleeved versions	C / P Maxflo standard catheter only	Davol sleeved catheter
Use						
Indicated for airway suctioning	Yes	Yes	Yes	Yes	Yes	Yes
Can be placed in-circuit	Yes	Yes	Yes	No	No	No
Used on pediatric and adults	Yes	Yes	Yes	Yes	Yes	Yes
Indicated as a disposable	Yes	Yes	Yes	Yes	Yes	Yes
Indicated for 24 hour use	Yes	Yes	Yes	No	No	No
Can be used with endotracheal and tracheostomy tubes	Yes	Yes	Yes	Yes	Yes	Yes
Design						
Lightweight construction	Yes	Yes	Yes	Yes	Yes	Yes
Various diameters of catheters	Yes	Yes	Yes	Yes	Yes	Yes
Different lengths for endotracheal and tracheostomy tubes	Yes	Yes	Yes	No	No	No
markings indicating length	Yes	Yes	Yes	Yes	Yes	Yes

110

**Non-Confidential Summary of Safety and Effectiveness
(continued)**

Comparison to predicate devices (continued)

Attribute	Continuous Ventilating Systems			Standard Catheter Only		Devol sleeved catheter
	Hudson RCI Soft Tech	Ballard Trach Care	Concord-Portax Steri-cath	Hudson RCI Catheter & sleeved versions	C / P Maxflo standard catheter only	
Design (continued)						
Has marking indicating when fully withdrawn	Yes	Yes	Yes	N/A	N/A	N/A
Single lumen design	Yes	Yes	Yes	Yes	Yes	Yes
Double lumen design	Yes	Yes	Yes	No	No	No
Has irrigation port(s)	Yes	Yes	Yes	No	No	No
Has a protective sleeve	Yes	Yes	Yes	No / Yes	No	Yes
Patient adapter connector to ventilator circuit and airway connector	Yes	Yes	Yes	N/A	N/A	N/A
Normally closed Suction control valve	No	Yes	Yes	No	No	No
Normally open suction control valve	Yes	No	No	Yes	Yes	Yes
Permits suctioning and ventilation to be done at the same time	Yes	Yes	Yes	No	No	No
Has a method, washer or duckbill valve to isolate the sleeve from the patient circuit	Yes	Yes	Yes	No	No	No
Catheter is completely out of patient circuit when withdrawn	Yes	No	No	Yes	Yes	Yes
Connects to suction tubing	Yes	Yes	Yes	Yes	Yes	Yes
Patient adapter - 15 / 22 mm fittings	Yes	Yes	Yes	N/A	N/A	N/A
Offer swivel capabilities	Yes	Yes	Yes	N/A	N/A	N/A
Can be left attached to patient airway connector and ventilator circuit when not in use	Yes	Yes	Yes	N/A	N/A	N/A
Lumen for secretion flow obstructed by suction valve control open/close mechanism	No	Yes	Yes	No	No	No
Has a filter in Suction Control Valve to reduce aerosols from contaminating environment	Yes	No	No	Yes	No	No
Suction control valve lockout to prevent accidental suctioning	Yes	Yes	No	Yes	No	No

**Non-Confidential Summary of Safety and Effectiveness
(continued)**

Comparison to predicate devices (continued)

Attribute	Continuous Ventilating Systems			Standard Catheter Only		Davol sleeved catheter
	Hudson RCI Soft Tech	Ballard Trach Care	Concord-Portex Steri-cath	Hudson RCI Catheter & sleeved versions	C / P Maxiflo standard catheter only	
Materials						
Catheter - PVC	Yes	Yes	Yes	Yes	Yes	Yes
Patient adapter and suction control valve	PS, PP, PE, ABS	PS, ABS	PS, ABS	PS, PP, PE, ABS	PS, PP, PE	PS, PP, PE
Duckbill valve / catheter wiper - PVC or silicone	Yes	Yes	Yes	N/A	N/A	N/A
Sleeve - PE	Yes	Yes	Yes	N/A / Yes	N/A	Yes
Packaging						
Offered sterile	Yes	Yes	Yes	Yes	Yes	Yes
Packaged with prefilled saline / water vials	Yes	Yes	Yes	No	No	No
Packaged with flex tube	Yes	Yes	Yes	N/A	N/A	N/A
Packaged with Airway disconnect wedge	Yes	No	Yes	N/A	N/A	N/A
Performance						
Allows ventilation during suctioning	Yes	Yes	Yes	No	No	No
Reduces patient oxygen desaturation	Yes	Yes	Yes	No	No	No
Filter media in suction control valve reduces potential contamination of environment from aerosols generated during suctioning	Yes	No	No	Yes	No	No

B. Conclusion

No differences which would affect the intended use, the application, the safety or the effectiveness between the Hudson RCI oral suction catheters described in this submission, and the legally marketed predicate devices listed above, have been identified.

112