510(k) SUMMARY
Rusch® Intermittent Urethral Catheters

Name, Address, Phone and Fax Number of Applicant

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Device Name

Trade Name:	Rusch® Intermittent Urethral Catheters
Common/Usual Name:	Urological Catheter
Regulation Number:	21 CFR 876.5130
Regulation Name:	Urological catheter and accessories
Regulation Class:	II
Product Code:	EZC - catheter, coude EZD - catheter, straight
Panel:	Gastroenterology/Urology

Predicate Device

Rusch® Intermittent Urethral Catheters –K033023

Device Description

The Rusch® Intermittent Urethral Catheters are single use, uncoated, disposable and sterile. The catheter is comprised of a tip, shaft, and funnel. The catheter tube is made of poloyvinylchloride (PVC), the tip of a PVC/liquid colored PVC which is cured to the tube and a catheter funnel also made of PVC. The dimensions range from Charrièr (Ch.) Ch. 10 to Ch. 24 which is a range of 3.3 mm to 7.9 mm in Outer Diameter with a length 40 cm. The catheters are produced with two different tips – Tiemann and Nelaton-Robinson. Each catheter size has a color-coded tip.

The Nelaton-Robinson catheters have a size range from 10 Ch. to 24 Ch. and have two drainage holes. The Tiemann catheters have a size range from 12 Ch. to 24 Ch. and also have two drainage holes. Additionally the Tiemann and Nelaton-Robinson catheters also contain funnel adhesive solution to which the funnel is adhered to the shaft and hot embossing film or tint for printing text on the catheter.

Indications for Use

The Intermittent Urethral Catheters are indicated for routine drainage of fluids from the bladder. These catheters are not intended or designed for indwelling use.

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Contraindications
Insuperable obstruction of the urethra. However, the suitability of each patient must be individually assessed by a physician or other suitably qualified personnel.

Substantial Equivalence
The subject device is substantially equivalent to the predicate device:

Features	Teleflex Medical Rusch Intermittent Urethral Catheters (Subject Device)	Rusch Urethral Intermittent Catheters (Predicate Device-K033023)	Comparison	
			Similarities	Differences
Classification Name	Catheter, Urological	Catheter, Urological	Devices are the same	None
Regulation Number	876.5130	876.5130	Devices are the same	None
Class	II	II	Devices are the same	None
Device Description	The Intermittent Urethral Catheters consists of a tubular shaft with attached funnel as connecting device. PVC material used in the catheter. The product sizes range from 10 Ch. to 24 Ch. The device shaft is uncoated.	The Intermittent Urethral Catheters consists of a tubular shaft with attached funnel as connecting device. The PVC material used in the catheter. The product sizes range from 6 Ch. to 24 Ch. The device shaft may be uncoated or hydrophilic coated.	Both devices are intended for intermittent catheterization.	The predicate, Intermittent Urethral Catheters, are offered with or without hydrophilic coating and have a wide range of sizes. The subject device shaft does not have a hydrophilic coating, it is uncoated.

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Indication for Use	The Intermittent Urethral Catheters are indicated for routine drainage of fluids from the bladder. These catheters are not intended or designed for indwelling use.	The Intermittent Urethral Catheters are sterile, single-use, flexible tubular devices that are inserted through the urethra and used to pass fluids to or from urinary tracts.	Both the predicates and subject catheters are sterile, single-use devices that pass fluids from the bladder/urinary tract.	The predicate devices intended use ***includes*** passage of fluids ***to or from*** the urinary tract. The subject Intermittent Urethral Catheters ***do not include*** the intended use of administration of fluids ***to*** the urinary tract.
Contraindications	Insuperable obstruction of the urethra. However, the suitability of each patient must be individually assessed by a physician or other suitably qualified personnel.	None known	There are no known contraindications for the predicate devices.	The subject Intermittent Urethral Catheters has a contraindicatio n.
Single Use	Yes	Yes	Devices are the same	None
Size Range	10 Ch. - 24 Ch.	6 Ch. - 24 Ch.	The subject Intermittent Urethral catheters sizes are included within the range of the predicate devices.	The predicate devices have a larger size range.
Overall Length	Nominal 40 cm	Nominal 40 cm	Devices are the same	None
Shaft	Tubular	Tubular	Devices are the same	None
Shaft Material			Both devices are	The subject

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	PVC	PVC	made with PVC	device is made with different plasticizer
Funnel Material	PVC	PVC	Both devices are made with PVC	The subject device is made with different plasticizer
Coating	Uncoated	Uncoated or Hydrophilic Coated	Both the predicate and subject Intermittent Urethral Catheters have uncoated catheters.	The predicate, Intermittent Urethral Catheters, also has coated catheters.
Biocompatibility	Evaluation and testing within the risk management process ISO 10993-1	Evaluation and testing within the risk management process ISO 10993-1	Biocompatibility studies of the devices conclude that the materials are safe for the intended use	None
Principal of Operation – Short Description of Use	• Peel package open • Insert catheter • Empty bladder • Withdraw catheter • Dispose device	• Peel package open • Insert catheter • Empty bladder • Withdraw catheter • Dispose device	Devices are the same	None
Catheter Tip Configurations	Tiemann and Nelaton- Robinson	Tiemann, Nelaton-Robinson, and Olive	The Tiemann and Nelaton-Robison configurations are offered for the predicate and subject devices.	The Olive tip configuration is offered for the predicate device.
Eyelets	Yes	Yes	Devices are the same	None
Primary Packaging	Paper and film peel back	Paper and film peel back	Devices are the same	None
Secondary Packaging	Corrugated box, quantity 50	Corrugated box, quantity100		The unit quantities in the secondary

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			Secondary packaging material is the same	packaging are different for the predicate than for the subject device.
Shipper Case	Corrugated board	Corrugated board	Devices are the same	None
Sterile	Yes	Yes	Devices are the same	None
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Devices are the same	None
Shelf-life	5 Years	3 Years	Both devices have a shelf-life of at least 3 years	The subject device, Intermittent Urethral Catheters, have a shelf-life of 5 years.

Non-clinical Performance testing
The bench testing performed verifies that the performance of the subject **Intermittent Urethral Catheters** are substantially equivalent in terms of critical performance characteristics to the predicate device. These tests include:

- Flow Rate
- Catheter Tensile properties
- Break Strength
- Cytotoxicity ISO 10993-5
- Sensitization ISO 10993-10
- Skin Irritation ISO 10993-10

Conclusion
The **Intermittent Urethral Catheters** have demonstrated through comparison of design features and performance testing that the proposed device and the predicate device are substantially equivalent. Performance test results demonstrate that the subject device meets its intended use and is as safe, as effective, and performs as well as or better than the legally marketed predicate device. It is for these reasons that the subject device can be found substantially equivalent.