A-001-1

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510(k) Summary

K181971
Bander Ureteral Diversion Stent Set
Dretler Ureteroscopy Stent Set
21 CFR §807.92
Date Prepared: April 4, 2019

Submitted By:

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Device Information:

Trade Name:	**Bander Ureteral Diversion Stent Set** **Dretler Ureteroscopy Stent Set**
Common Name:	Ureteral stent
Classification Name:	Ureteral stent,
Regulation:	21 CFR §876.4620
Product Code:	FAD, Class II

Predicate Device:

The Percuflex™ Urinary Diversion Stent Set (K830803, Boston Scientific) is designed to be used following percutaneous, endoscopic, or operative procedures. The design features a pigtail curl on the distal end to prevent migration and a luer-lock connection on the proximal end. The stent has graduation markings to aid in placement. The set includes two stents (color-coded left and right sides), a guidewire, catheter adapters, and a drainage bag connector.

Device Description:

The Bander Ureteral Diversion Stent

The Bander Ureteral Diversion Stent Set features a pigtail ureteral stent constructed of either silicone or polyurethane. The stent ranges from 4.7 to 8.4 French and the overall lengths range from 70 to 90 centimeters. The pigtail retention coil can be open or closed, tapered or non-tapered, but all configurations contain 6 evenly space sideports. Sideports continue for the first

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10 centimeters of the stent body from the pigtail. In addition to the 90° rotated sideports, some of the stents feature ink markings to aid in placement.

The Bander Ureteral Diversion Stents Sets are supplied with either one or two stents. When two stents are included, a right and left are color-coded red and blue, respectively.

The Bander Ureteral Diversion Stent Sets are also supplied with a straight wire guide.

The accessories supplied with the Bander Ureteral Diversion Stent Sets include an adapter with an O-ring and a catheter retainer.

The Dretler Ureteroscopy Stent

The Dretler Ureteroscopy Stent Set includes a 4.7, 6.0, or 8.4 French stent. The stent is manufactured using a polyurethane material and has a single pigtail at the distal end with 3 evenly spaced sideports. The stent comes with incremental ink markings and is 125 centimeters in length.

The Dretler Ureteroscopy Stent Sets are supplied with an accessory connector with an O-ring and a wire guide.

Intended Use:

The Bander Ureteral Diversion Stent

The Bander Ureteral Diversion Stent Sets are used for intraoperative placement to stent the ureter and provide drainage of urine from the kidney to the external stoma during ureteroileal conduit construction and continent urinary diversions.

The Dretler Ureteroscopy Stent

The Dretler Ureteroscopy Stent Set is intended to be used for post-ureteroscopy stenting of the ureter.

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Comparison to Predicates:

The Bander Ureteral Diversion Stent Set

		PREDICATE DEVICE	SUBJECT DEVICE
		Percuflex™ Urinary Diversion Stent Set (K830803)	**Bander Ureteral Diversion Stent Set (Subject of this Submission)**
Manufacturer		Boston Scientific	Cook
Regulation Number		Unclassified	21 CFR §876.4620
Product Code		LJE	FAD
Classification Name		Catheter, Nephrostomy	Stent, Ureteral
Device Class		II	Identical
Indications for Use		The Percuflex™ Urinary Diversion Stent Set is used for drainage following percutaneous, endoscopic, or operative procedures.*	Used for intraoperative placement to stent the ureter and provide drainage of urine from the kidney to the external stoma during ureteroileal conduit construction and continent urinary diversions.
Model Number		M0061602XX	025XXX[-XX]
Kit Components		• Stent • Wire guide • Catheter Connectors* • Tube Connectors*	• Stent • Wire guide • Drainage tube adapter • Stent retainer
Stent	**Outer Diameter (Fr)**	Pediatric: 4.0, 5.0, 6.0 Adult: 6, 7, and 8	Adult: 4.7, 6.0, 7.2, and 8.4
	Length (cm)	Pediatric: 30 Adult: 70	Adult: 70, 75, and 90
	Material	C-Flex Thermoplastic Elastomer	silicone or polyurethane
	Tip Configuration	Closed and Open Tip	Identical
	Sideport Size (gage)	Unknown	Curl: 18, 19, or 21 Shaft: 17, 18, or 21
	Ink	Unknown	Black Ink
Indwelling Time		≤ 90 days*	≤ 90 days
Packaging		Unknown	Tyvek polyethylene peel-open pouch
Sterilization		Unknown	EtO
Shelf Life		Unknown	3 years

*If information was not specified within the predicate 510(k), then information was obtained from currently available marketing information and is discussed further in the Substantial Equivalence discussion as appropriate. See Appendix F for predicate marketing data.

The subject device, the Bander Ureteral Diversion Stent Set is similar to the Percuflex™ Urinary Diversion Stent Set (K830803, Boston Scientific) in terms of intended use and technological characteristics. The minor differences from the predicate devices include:

- Similar but not identical indications for use
- Product Code
- Additional stent dimensions
- Different stent materials
- Indwell time
- Packaging

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- Sterilization
- Shelf-life

Reference devices used to help support a substantial equivalence determination for the Bander Ureteral Diversion Stent include:

- Cook Black Silicone Filiform Double Pigtail Stent Set (K172017)
- Surgitek Urinary Diversion Stent (K800109)
- Bard Ureteral Stent (K823487)

The Dretler Ureteroscopy Stent Set

	PREDICATE DEVICE	SUBJECT DEVICE
	Percuflex™ Urinary Diversion Stent Set (K830803)	**Dretler Ureteroscopy Stent Set (Subject of this Submission)**
Manufacturer	Boston Scientific	Cook
Regulation Number	Unclassified	21 CFR §876.4620
Product Code	LJE	FAD
Classification Name	Catheter, Nephrostomy	Stent, Ureteral
Device Class	II	Identical
Indications for Use	The Percuflex™ Urinary Diversion Stent Set is used for drainage following percutaneous, endoscopic, or operative procedures.*	Used for post-ureteroscopy stenting of the ureter.
Model Number	M0061602XX	0255XX[-XX]
Kit Components	• Stent • Wire guide • Catheter Connectors* • Tube Connectors*	• Stent • Wire guide • Catheter adapter
Stent Outer Diameter (Fr)	Pediatric: 4.0, 5.0, 6.0 Adult: 6, 7, and 8	4.7, 6, and 8.4
Stent Length (cm)	Pediatric: 30 Adult: 70	125
Stent Material	C-Flex Thermoplastic Elastomer	Polyurethane
Stent Tip Configuration	Closed and Open Tip	Open Tip
Sideport Size (gage)	Unknown	18, 19, or 21
Stent Marker Band Material	Unknown	Black Ink
Indwelling Time	≤ 90 days*	≤ 90 days
Packaging	Unknown	Tyvek polyethylene peel-open pouch
Sterilization	Unknown	EtO
Shelf Life	Unknown	3 years

*If information was not specified within the predicate 510(k), then information was obtained from currently available marketing information and is discussed further in the Substantial Equivalence discussion as appropriate. See Appendix F for predicate marketing data.

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The subject device, the Dretler Ureteral Diversion Stent Set is similar to the Percuflex™ Urinary Diversion Stent Set (K830803, Boston Scientific). The Dretler Ureteral Diversion Stent Set and the predicate are similar in that these devices have similar designs, intended use, and technological characteristics. The modifications from the predicate devices include:

- A more specific indications for use
- Product Code
- Additional stent dimensions
- Characteristically similar material
- Unknown predicate materials
- Indwell time
- Packaging
- Sterilization
- Shelf-life

Technological Characteristics:

The following tests have been conducted to ensure reliable design and performance under the specified testing parameters on both subject devices. These tests include:

- MRI Safety Testing
- Dimensional
- Tensile Strength
- Shaft and Curl Elongation
- Retention Strength
- Flow Rate
- Radiopacity
- Kink
- Compatibility with components
- Artificial Urine Soak
- Accelerated Aging

The Black Silicone Filiform Double Pigtail Stent Set manufactured by Cook Incorporated (K172017) was used as a reference device to help support a substantial equivalence determination for the Dretler Ureteroscopy Stent Set.

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Conclusion:

Packaging, sterilization, and shelf-life of the predicate device are not known, however, testing on the subject device has been performed on the subject device in accordance with all applicable standards and device requirements. The results of these tests show that the subject devices, Bander Ureteral Diversion Stent Set and Dretler Ureteroscopy Stent Set, met the design input requirements based on the intended use. Therefore, these data support the conclusion that this device does not raise new questions of safety or effectiveness and that the Bander Ureteral Diversion Stent Set is substantially equivalent to the predicate device the Percuflex™ Urinary Diversion Stent Set (K830803).

Furthermore, the results of these tests show that the subject Dretler Ureteroscopy Stent Set met the design input requirements based on the intended use. Therefore, these data support the conclusion that this device does not raise new questions of safety or effectiveness and that the subject Dretler Ureteroscopy Stent Set is substantially equivalent to the predicate device, the Percuflex™ Urinary Diversion Stent Set (K830803).