K182828 510(k) Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR § 807.92.

Submitter/ Owner	Surgical Instrument Service and Savings (dba Medline ReNewal) 1500 NE Hemlock Ave., Redmond, OR 97756	
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Device Name and Classification	Proprietary/Trade Name:	Medline ReNewal Reprocessed Carter-Thomason Needle-Point Suture Passer Instrument Set
	Common or Usual Name	Suture Passer, Carter-Thomason CloseSure System
	Regulatory Name/Reference	Endoscope and accessories reprocessed, 21 CFR § 876.1500
	Regulatory Class	Class II
	Product Code	NLM
	Panel	Gastroenterology/Urology
Predicate Device	510(k) Number	K980123
	Proprietary or Trade Name	Carter-Thomason Needle-Point Suture Passer Instrument Set
	Common or Usual Name	Suture Passer, Carter-Thomason CloseSure System
	Regulatory Name/Reference	Endoscope and accessories, 21 CFR § 876.1500
	Regulatory Class	Class II
	Product Code	GCJ
	Panel	Gastroenterology/Urology
	Manufacturer	Louisville Laboratories 2400 Crittenden Dr., Louisville, KY 40217-1865
Device Description	The Medline ReNewal Reprocessed Carter-Thomason Suture Passer Set (models CTI-512N, CTI-1015N, PG-15S, and PG-5/10) is a sterile, single-case use, hand-held suture grasping device that is designed to pass suture through soft tissue.	
Indications for use	The Medline ReNewal Reprocessed Carter-Thomason Needle-Point Suture Passer is indicated to pass suture through soft tissues of the body during endoscopic/laparoscopic surgery.	
Technological Characteristics	The technological characteristics and the fundamental scientific technology of the subject devices are identical to the predicate device. The proposed devices are a reprocessed version of the predicate devices. K980123 Carter-Thomason Needle Point Suture Passer Instrument Set was used as the primary predicate to support intended use, technological characteristics, and functional performance specifications.	

Performance Testing	The functional characteristics of the proposed devices have been evaluated and found to be equivalent to the predicate devices based on the following tests:
	• simulated use;
	• device integrity;
	• cleaning:
	  ○ protein, carbohydrates and hemoglobin;
	• biocompatibility:
	  ○ cytotoxicity, sensitization, irritation; pyrogenicity, and acute systemic toxicity;
	• performance qualification;
	• sterilization validation; and
	• product stability.

Summary Table: Predicate and Medline ReNewal Reprocessed Carter-Thomason Needle Point Suture Passer Instrument Set device comparison chart.

Device Characteristics	**Predicate**	**Proposed**	**Comparison**
	Louisville Laboratories Carter-Thomason Needle Point Suture Passer Instrument Set	**Medline ReNewal Reprocessed Carter-Thomason Needle Point Suture Passer Instrument Set**	**As Stated**
510(k)	K980123	K182828	N/A
Model Numbers	CTI-512N CTI-1015N Carter-Thomason CloseSure System XL	CTI-512N CTI-1015N PG – 15S PG-5/10	Same
Common Name	Endoscope and accessories	Endoscope and accessories	Same
Regulation No.	21 CFR § 876.1500	21 CFR § 876.1500	Same
Regulatory Class	Class II	Class II	Same
Product Code	GCJ	NLM	As stated
Indications for Use	The Needle-Point Suture Passer is indicated to pass suture through soft tissues of the body during endoscopic/laparoscopic surgery.	The Medline ReNewal Reprocessed Needle-Point Suture Passer is indicated to pass suture through soft tissues of the body during endoscopic/laparoscopic surgery.	Same
Technological Characteristics	The Carter-Thomason Suture passer is a sterile, single-case use, hand-held suture grasping device that is designed to pass suture through soft tissue during endoscopic/laparoscopic surgeries.	The Carter-Thomason Suture passer is a sterile, single-case use, hand-held suture grasping device that is designed to pass suture through soft tissue during endoscopic/laparoscopic surgeries.	Same

Conclusion	Based on comparisons of the indications for use, intended use, technological characteristics, and performance data to the predicate devices, Medline ReNewal Reprocessed Carter-Thomason Needle Point Suture Passer Instrument Sets are substantially equivalent to the predicate devices.