DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182828

Device Name
Medline ReNewal Reprocessed Carter-Thomason Needle-Point Suture Passer Instrument Set

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K182588 Reprocessed Carter-Thomason CloseSure Devices included in Submission:

OEM Device Model[a]	Device Name	OEM
CTI-512N	Carter Thomason CloseSure System (Carter Thomason Suture Passer, 5-mm Pilot Guide, 10/12-mm Pilot Guide)	Louisville Laboratories, Inc.
CTI-1015N	Carter Thomason CloseSure System (Carter Thomason Suture Passer, 10/12-mm Pilot Guide, 115-mm Pilot Guide)	Louisville Laboratories, Inc.
PG-15S	15-mm Pilot Guide	Louisville Laboratories, Inc.
PG-5/10	5-mm Pilot Guide, 10/12 mm Pilot Guide	Louisville Laboratories, Inc.

[a] OEM = original equipment manufacturer.