November 30, 2021

Summitt Medical LLC
Debra Kridner
President Debra J Kridner Consulting LLC
815 Vikings Pkwy, Suite 100
St. Paul, Minnesota 55121

Re: K210836
Trade/Device Name: InstruSafe Instrument Protection System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: October 28, 2021
Received: October 29, 2021

Dear Debra Kridner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Clarence W. Murray, III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210836

Device Name

lnstruSafe® Instrument Protection System

Indications for Use *(Describe)*

InstruSafe® Instrument Protection System cassettes(trays) are used to organize and protect other medical devices that are sterilized by a healthcare provider. lnstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during STERIZONE VP4 sterilization Cycle 1. The lnstruSafe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed wrap or Aesculap rigid container. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility.
Summit Medical has validated the use of the InstruSafe Instrument Protection System cassettes in Cycle 1 of the STERIZONE VP4 sterilizer through demonstrations of sterilization efficacy using representative samples of medical devices including general instruments, rigid and semi-rigid instruments with lumens, and flexible endoscopes. The validation provided information that has been used to establish design limits that are applied across the range of InstruSafe Instrument Protection System cassettes to ensure that all models fall within the validated limits for cassette ventilation, internal shelving, and weight:

- Minimum ventilation-to-volume ratio, general instruments: 0.073
- Minimum ventilation-to-volume ratio, flexible endoscopes: 0.263
- Maximum number of internal shelves: Two (2)
- Maximum cassette weight (including contents): 25 lbs/cassette

Refer to Table for the validated loads using InstruSafe Instrument Protection System cassettes. Refer to the sterilizer manufacturer's instructions for use to ensure that loads do not exceed the claimed limits for the sterilizer.

Table – Description of InstruSafe Instrument Protect System Loads.

Representative of STERIZONE® VP4 Sterilizer Validation Load No. (K190260)	**Summit Medical Validation Load Description**	**Total Load Weight (excludes the 25-lbs. loading rack)**
4	**Load 4a:** Consisted of the load limit for rigid and semi-rigid channeled instruments: • **Three (3) double channel semi-rigid endoscopes** (ureteroscope – 0.7 mm × 500 mm and 1.1 mm × 500 mm) were packaged, one (1) per cassette, in **three (3)** IN-7323-R **cassettes**. • Additional rigid channel instruments were added to reach a **total of 15 channels**. Each cassette included appropriate silicone instrument holders and was wrapped. **Load 4b:** Consisted of the load limit for rigid and semi-rigid channeled instruments: • **Three (3) double channel semi-rigid endoscopes** (ureteroscope – 0.7 mm × 400 mm and 1.1 mm × 400 mm) were packaged, one (1) per cassette, in **three (3)** IN-0007-TF **cassettes**. • Additional rigid channeled instruments were added to reach a **total of 15 channels**. Each cassette included appropriate silicone instrument holders and was placed in an Aesculap JM440 rigid container.	Load 4a = 5 lbs/cassette, 15 lbs total Load 4b = 11 lbs/cassette, 33 lbs total

Representative of STERIZONE® VP4 Sterilizer Validation Load No. (K190260)	Summit Medical Validation Load Description	Total Load Weight (excludes the 25-lbs. loading rack)
7	**Summit Medical Validation Load 7a:** Consisted of the load weight limit for general medical instruments representing the following geometries: • Box-lock hinge • Pivot hinge • Luer-lock General medical instruments were spread across **three (3)** IN-7323-R **cassettes** with appropriate silicone holders, each weighing 25 lbs. The cassettes were wrapped. **Summit Medical Validation Load 7b:** Consisted of the load weight limit for general medical instruments representing the following geometries: • Box-lock hinge • Pivot hinge • Luer-lock General medical instruments were spread across **three (3)** IN-0006-TF **cassettes** with appropriate silicone holders. Cassettes were placed in Aesculap JM440 containers, each weighing 25 lbs.	Load 7a = 25 lbs/cassette 75 lbs total Load 7b = 25 lbs/cassette 75 lbs total
8	**Summit Medical Validation Load 8a:** Consisted of the load limit of **five (5) total flexible endoscope channels** in wrapped cassettes: • **Two (2) double-channel flexible endoscopes** (ureteroscopes – 1 mm x 850 mm and 1 mm x 989 mm) were packaged, one (1) per cassette, in IN-0003-R cassettes. • **One (1) single-channel flexible endoscope** (ureteroscope – 1 mm x 850 mm) was packaged in an IN-0004-R cassette. Cassettes included appropriate silicone holders and were wrapped. **Summit Medical Validation Load 8b:** Consisted of the load limit of **four (4) total flexible endoscope channels** in cassettes packaged in rigid containers: • **Two (2) double channel flexible endoscopes** (ureteroscope – 1 mm x 850 mm and 1 mm x 989 mm) were packaged, one (1) per cassette, in IN-0003-TF cassettes with appropriate silicone holders. Each cassette was placed inside an Aesculap JM442 container.	Load 8a = 4.3 lbs/cassette, 13 lbs total Load 8b = 8.3 lbs/cassette, 25 lbs total

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY- K210836

Following is a summary of 510(k) is in accordance with 21 CFR 807.92

Date Prepared:	November 24, 2021
Applicant:	Summit Medical LLC 815 Vikings Parkway, Suite 100 St. Paul, MN 55121 | USA Ph: (651) 789-3966
Official Correspondent:	Debra Kridner President Debra J Kridner Consulting, LLC Regulatory Affairs Email: dkridner@comcast.net
Subject Device	
Trade/Device Name:	InstruSafe® Instrument Protection Systems
Common or Usual Name:	Instrument Tray, Sterilization Tray, Sterilization Cassettes, Instrument Delivery System
Device Classification Regulation Number	21 CFR 880.6850
Classification Name:	Sterilization wrap containers, trays, cassettes and other accessories
Regulatory Class:	Class II
Product Code:	KCT
Predicate Device Details	
Predicate Device:	K150540 – Instru-Safe Instrument Protection System – SUMMIT MEDICAL, INC. 21 CFR 880.6850 - KCT

Device Description:

Summit Medical LLC InstruSafe Instrument Protection Systems are cassettes/trays used to enclose and hold surgical instruments and instrument accessories in an organized manner during the sterilization process and subsequent storage and transportation. The cassettes/trays do not have direct patient contact. The cassettes/trays by themselves do not maintain sterility. The cassettes/trays are different sizes of the same basic configuration: a rectangular base with latchable cover. The cassettes/trays have perforations to allow sterilant penetration. The cassettes/trays contain silicone inserts in the base and/or

cover to hold, organize, and protect the surgical instruments within the cassette/tray during the sterilization process and subsequent storage and transportation.

Indications for Use:

InstruSafe® Instrument Protection System cassettes (trays) are used to organize and protect other medical devices that are sterilized by a healthcare provider. lnstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during STERIZONE VP4 sterilization Cycle 1. The lnstruSafe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed wrap or Aesculap rigid container. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility.
Summit Medical has validated the use of the InstruSafe Instrument Protection System cassettes in Cycle 1 of the STERIZONE VP4 sterilizer through demonstrations of sterilization efficacy using representative samples of medical devices including general instruments, rigid and semi- rigid instruments with lumens, and flexible endoscopes. The validation provided information that has been used to establish design limits that are applied across the range of InstruSafe Instrument Protection System cassettes to ensure that all models fall within the validated limits for cassette ventilation, internal shelving, and weight:

- Minimum ventilation-to-volume ratio, general instruments: 0.073
- Minimum ventilation-to-volume ratio, flexible endoscopes: 0.263
- Maximum number of internal shelves: Two (2)
- Maximum cassette weight (including contents): 25 lbs/cassette

Refer to the table below for the validated loads using InstruSafe Instrument Protection System cassettes. Refer to the sterilizer manufacturer's instructions for use to ensure that loads do not exceed the claimed limits for the sterilizer.

Table – Description of InstruSafe Instrument Protect System Loads.

Representative of STERIZONE® VP4 Sterilizer Validation Load No. (K190260)	Summit Medical Validation Load Description	Total Load Weight (excludes the 25-lbs. loading rack)
4	**Load 4a:** Consisted of the load limit for rigid and semi-rigid channeled instruments: • **Three (3) double channel semi-rigid endoscopes** (ureteroscope – 0.7 mm × 500 mm and 1.1 mm × 500 mm) were packaged, one (1) per cassette, in **three (3)** IN-7323-R **cassettes**. • Additional rigid channel instruments were added to reach a **total of 15 channels**. Each cassette included appropriate silicone instrument holders and was wrapped. **Load 4b:** Consisted of the load limit for rigid and semi-rigid channeled instruments: • **Three (3) double channel semi-rigid endoscopes** (ureteroscope – 0.7 mm × 400 mm and 1.1 mm × 400 mm) were packaged, one (1) per cassette, in **three (3)** IN-0007-TF **cassettes**. • Additional rigid channeled instruments were added to reach a **total of 15 channels**. Each cassette included appropriate silicone instrument holders and was placed in an Aesculap JM440 rigid container.	Load 4a = 5 lbs/cassette, 15 lbs total Load 4b = 11 lbs/cassette, 33 lbs total

Representative of STERIZONE® VP4 Sterilizer Validation Load No. (K190260)	Summit Medical Validation Load Description	Total Load Weight (excludes the 25-lbs. loading rack)
7	**Summit Medical Validation Load 7a:** Consisted of the load weight limit for general medical instruments representing the following geometries: • Box-lock hinge • Pivot hinge • Luer-lock General medical instruments were spread across **three (3)** IN-7323-R **cassettes** with appropriate silicone holders, each weighing 25 lbs. The cassettes were wrapped. **Summit Medical Validation Load 7b:** Consisted of the load weight limit for general medical instruments representing the following geometries: • Box-lock hinge • Pivot hinge • Luer-lock General medical instruments were spread across **three (3)** IN-0006-TF **cassettes** with appropriate silicone holders. Cassettes were placed in Aesculap JM440 containers, each weighing 25 lbs.	Load 7a = 25 lbs/cassette 75 lbs total Load 7b = 25 lbs/cassette 75 lbs total

Representative of STERIZONE® VP4 Sterilizer Validation Load No. (K190260)	Summit Medical Validation Load Description	Total Load Weight (excludes the 25-lbs. loading rack)
8	**Summit Medical Validation Load 8a:** Consisted of the load limit of **five (5) total flexible endoscope channels** in wrapped cassettes: • **Two (2) double-channel flexible endoscopes** (ureteroscopes – 1 mm x 850 mm and 1 mm x 989 mm) were packaged, one (1) per cassette, in IN-0003-R cassettes. • **One (1) single-channel flexible endoscope** (ureteroscope – 1 mm x 850 mm) was packaged in an IN-0004-R cassette. Cassettes included appropriate silicone holders and were wrapped. **Summit Medical Validation Load 8b:** Consisted of the load limit of **four (4) total flexible endoscope channels** in cassettes packaged in rigid containers: • **Two (2) double channel flexible endoscopes** (ureteroscope – 1 mm x 850 mm and 1 mm x 989 mm) were packaged, one (1) per cassette, in IN-0003-TF cassettes with appropriate silicone holders. Each cassette was placed inside an Aesculap JM442 container.	Load 8a = 4.3 lbs/cassette, 13 lbs total Load 8b = 8.3 lbs/cassette, 25 lbs total

Technological Characteristic Comparison Table

Comparison of Subject Device to Predicate Device	Subject Device InstruSafe® Instrument Protection Systems (K210836)	Predicate Device InstruSafe® Instrument Protection Systems (K150540)	Comparison
Trade/Device Name	InstruSafe® Instrument Protection Systems	InstruSafe® Instrument Protection Systems	Same
Common or Usual Name	Instrument Tray, Sterilization Tray, Sterilization Cassettes, Instrument Delivery System	Instrument Tray, Sterilization Tray, Sterilization Cassettes, Instrument Delivery System	Same
Device Classification Regulation Number	21 CFR 880.6850	21 CFR 880.6850	Same
Classification Name:	Sterilization wrap containers, trays, cassettes and other accessories	Sterilization wrap containers, trays, cassettes and other accessories	Same
Regulatory Class:	II	II	Same
Product Code:	KCT	KCT	Same
Indications for Use	InstruSafe® Instrument Protection System cassettes (trays) are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during STERIZONE VP4 sterilization Cycle 1. The lnstruSafe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed wrap or Aesculap rigid container. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility. Summit Medical has validated the use of the InstruSafe Instrument Protection System cassettes in Cycle 1 of the STERIZONE VP4 sterilizer through demonstrations of sterilization efficacy using representative samples of medical devices including general instruments, rigid and semi-rigid instruments with lumens, and flexible endoscopes. The validation provided information that has been used to establish design limits that are applied across the range of InstruSafe Instrument Protection System cassettes to ensure that all models fall within the validated limits for cassette ventilation, internal shelving, and weight: • Minimum ventilation-to-	Instru-Safe ® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. Instru-Safe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during Amsco V-PRO Low Temperature Sterilization Cycles. The Instru-Safe Instrument Protection System cassettes are intended to be used in conjunction with legally marketed wrap or Aesculap rigid container. The Instru-Safe Instrument Protection System cassettes are not intended on their own to maintain sterility.	Similar

	volume ratio, general instruments: 0.073 • Minimum ventilation-to-volume ratio, flexible endoscopes: 0.263 • Maximum number of internal shelves: Two (2) • Maximum cassette weight (including contents): 25 lbs/cassette Refer to the table located under the indications for use section for the validated loads using InstruSafe Instrument Protection System cassettes. Refer to the sterilizer manufacturer's instructions for use to ensure that loads do not exceed the claimed limits for the sterilizer.		

Technological Characteristics Comparison Table

Technological Characteristics/ Performance Comparison of Subject Device to Predicate Device	**Subject Device** **InstruSafe® Instrument Protection Systems** (K210836)	**Predicate Device** **InstruSafe® Instrument Protection Systems** (K150540)	**Comparison**
Material Composition	No changes from predicate device	The cassette contains components made of anodized aluminum, stainless steel, blue silicone, black silicone, polyester, ultem™ 1000	Same
Physical Properties	InstruSafe Instrument Protection System cassettes include - Perforated cassette base - Perforated cassette cover - Silicone inserts (hold-it / hold down) - Handles - Feet - Latches - Divider (optional) - Locating Post (optional) - Module (optional)	Instru-Safe Instrument Protection System cassettes include - Perforated cassette base - Perforated cassette cover - Silicone inserts (hold-it / hold down) - Handles - Feet - Latches - Divider (optional) - Locating Post (optional) - Module (optional)	Same
Chemical Properties	Not Applicable	Not Applicable	_
Configurations/ Dimensions	Various configurations / dimensions	Various configurations / dimensions	Same
Air permeance	Not Applicable	Not Applicable	_
Percent of surface perforations	Not Applicable	Not Applicable	_
Sterilant Penetration	Sterizone VP4 sterilizer with vapor hydrogen peroxide and ozone dual sterilant	Amsco V-PRO Low Temperature Sterilization Systems with vapor hydrogen peroxide sterilant	Similar Hydrogen peroxide base sterilants

Microbial Barrier Properties (Packaging Integrity)	Not Applicable	Not Applicable	_
Material Compatibility	No changes from predicate device	No changes from reference device (K133015)	Same
Toxicological Properties (Biocompatibility, including Sterilant Residue Limits)	MEM Elution Cytotoxicity (ISO 10993-5) Levels of residual hydrogen peroxide on materials met the limit for safety established by the sterilizer manufacturer (The limit for safety was provided in K141163 -TS03 Sterizone Sterilizer)	MEM Elution Cytotoxicity (ISO 10993-5) NA	Same
Shelf Life	Reusable (5 year accelerated shelf-life study)	Reusable (5 year accelerated shelf-life study)	Same

Technological Characteristics:

The technological characteristics of the subject device are identical to the predicate device. The cassettes / trays are made of identical materials and do not incorporate any new technological characteristics. The only change from the predicate to the subject device is in the sterilizer and the sterilant.

Performance Data:

All necessary testing has been performed for the InstruSafe® Instrument Protection System to demonstrate the device performs as intended and met the standards and test methodology listed below.

The InstruSafe® Instrument Protection System using the Sterizone sterilizer was qualified through the following tests:

- Sterilization efficacy with sterilization wraps and rigid containers
- Sterility maintenance
- Microbial aerosol challenge
- Sterilant Residual study
- Biocompatibility study
- Reusability study
- InstruSafe tray handle performance testing
- Cleaning validations (manual, mechanical, and ultrasonic)

Summary of Nonclinical Testing:

Test Methodology	Purpose	Acceptance Criteria	Results
Cleaning Validations (Manual, Mechanical, and Ultrasonic) FDA Guidance *Reprocessing Medical Devices in Health CareSettings: Validation Methods and Labeling* (Issued March 2015) AAMI TIR30:2011	The purpose of this study was to validate the effectiveness of manual, mechanical, and ultrasonic cleaning procedures specified in the Instructions for Use using the worst-case cassette in terms of product geometry, worst-case (coldest) processing temperatures, and artificial soil.	Micro BCA Protein Assay: Residual protein level ≤ 6.4 µg/cm^2 Total Organic Carbon assay: TOC ≤ 2.2 µg/cm^2	Pass
Sterilization Efficacy Validation: Half-Cycle Overkill Approach ANSI/AAMI/ISO 14937:2009	The purpose of the study was to demonstrate delivery of a minimum sterility assurance level (SAL) of 10^{-6} to biological indicators (BIs) at difficult to sterilize locations in medical devices when validation loads are processed in the InstruSafe Instrument Protection System cassettes. Both wraps and rigid containers were used as sterile barriers.	Three (3) consecutive half cycles in which all biological indicators (BIs) are inactivated. Minimum BI population: 1 x 10^6 CFU/BI	Pass
Sterility maintenance via simulated use and shelf-life testing using coupon sterility tests at end of shelf life. ANSI/AAMI/ISO 11607:2019 ANSI/AAMI ST77:2013/(R)2018	The purpose of the study was to demonstrate maintenance of sterility over the stated shelf life using simulated handling conditions when sterilization wrap is used as the sterile barrier for the worst-case cassette in terms of weight.	Sterility tests of coupons that were sterilized and stored in the wrapped cassettes shall be negative for growth after 366 days of simulated storage and handling.	Pass
Microbial Aerosol Challenge for Sterile Barrier Package Integrity	The purpose of the test was to demonstrate the integrity of sterilization wrap as a sterile barrier after exposure to Cycle 1 using a microbial aerosol challenge of ≥ 800 CFU/cm^2.	Sterility tests of coupons that were sterilized in Cycle 1 and then subjected to the microbial aerosol challenge in the wrapped cassette shall be negative.	Pass
Residual hydrogen peroxide testing ANSI/AAMI ST77:2013 ANSI/AAMI/ISO 11607-1:2019 ISO 10993-12:2012	The purpose of the test was to demonstrate that levels of residual hydrogen peroxide on cassette materials were below safe levels after a worst-case exposure of three (3) consecutive iterations of Cycle 1.	The extracted residual hydrogen peroxide on device materials shall not exceed 997 ± 142 µg/cm^2, which was established as a safe level in K141163.	Pass
Biocompatibility of Subject Device (by cytotoxicity testing) ANSI/AAMI/ISO 10993-5 ANSI/AAMI/ISO 10993-12	The purpose of this test is toevaluate the cytotoxicity potential of the test article using an in vitro cell culture assay.	Acceptance criterion: Non-cytotoxic a reactivity grade of ≤ 1 is scored based on histological interpretation of the test system.	Pass
Life Cycle / Simulated Use Life Validation FDA Guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* (issued March 2015)	The purpose of this test is to validate the service life of the trays as stated in the Instructions for Use.	Acceptance criteria: Visual inspection, component dimensional fit verification, functional closure/latch verification for 100 use cycles	Pass
Cassette handle safety test. ANSI/AAMI ST77:2013	The purpose of this test was to demonstrate that the handles on the InstruSafe cassettes could withstand a 100-lb load without deforming or failing.	No evidence of damage, deformation, or cracking of the handle after a 100-lb load is applied for 1 minute.	Pass

Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.