February 21, 2025

Medicom Asia-Pacific Holdings Ltd. Taiwan Branch.
℅ Uta Shih
Regulatory Affairs Manager
Sen Mu Technology Co., LTD.
15F.-2, No.1. Ln. 26, Minquan 1st Rd., Lingya Dist
Kaohsiung City, Taiwan 802
Taiwan

Re: K243431
Trade/Device Name: Medicom Sterilization Pouch and Reel
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG, JOJ
Dated: November 5, 2024
Received: January 21, 2025

Dear Uta Shih:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
Division Director
DHT4C: Division of Infection Control 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: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243431

Device Name
Medicom Sterilization Pouch and Reel

Indications for Use *(Describe)*
The Medicom Sterilization Pouch and Reel are intended to provide health care workers with an effective method to enclose devices, and they can use Single Pouch or Double Pouches intended for sterilization in the Steam or via Ethylene Oxide (EO). The recommended sterilization cycles are as follows:

Gravity steam at 121°C (250°F) for 30 minutes; Drying time of 25 minutes.
Pre-vacuum steam at 132°C (270°F) for 4 minutes; Drying time of 20 minutes.
Pre-vacuum steam at 134°C (273°F) for 4 minutes; Drying time of 20 minutes.
Ethylene Oxide (EO) with a concentration of 600 mg/L at 50°C (122°F) and 60% to 85% relative humidity for 120 minutes. Single Pouch: Aeration time of 5 days at 25°C (77°F). Double Pouches: Aeration time of 3 days at 25°C (77°F).

Furthermore, there are 3 thicknesses for health care workers to choose from as follows:

Pouch of Combination A: Medical grade paper 60g+laminated film 44μm
Pouch of Combination B: Medical grade paper 60g+laminated film 52μm
Pouch of Combination C: Medical grade paper 70g+laminated film 52μm

The Medicom Sterilization Pouch and Reel which are made with Paper maintains the sterility of the enclosed devices for up to 1 year post Steam or EO gas sterilization, and before sterilization has a maximum shelf life of 3 years from the date of manufacture. The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process.

The following table (Table 5-1 to Table 5-3) lists the model numbers of the Medicom Sterilization Pouch and Reel by type, model, dimensions, and max. load (lbs.):

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.

Table 5-1. The model numbers of Medicom Sterilization Pouch and Reel

(Medical grade paper 60g+laminated film 44μm: Type, Model and Dimension and Max. Load)

Pouch of Combination A: Medical grade paper 60g+laminated film 44μm			
Type	Dimension	Model	Max. Load (lb.)
Medicom Self-seal Pouch	57x127 mm	88015-4	0.03
Medicom Self-seal Pouch	70x254 mm	88000-4	0.32
Medicom Self-seal Pouch	89x159 mm	88005-4	0.20
Medicom Self-seal Pouch	89x191 mm	88001-4	0.27
Medicom Self-seal Pouch	89x254 mm	88010-4	0.44
Medicom Self-seal Pouch	89x286 mm	88003-4	0.50
Medicom Self-seal Pouch	83x330 mm	88004-4	0.57
Medicom Self-seal Pouch	89x617 mm	88006-4	1.23
Medicom Self-seal Pouch	108x305 mm	88009-4	0.70
Medicom Self-seal Pouch	133x190 mm	88011-4	0.48
Medicom Self-seal Pouch	133x279 mm	88025-4	0.79
Medicom Self-seal Pouch	133x311 mm	88013-4	0.87
Medicom Self-seal Pouch	133x330 mm	88014-4	0.96
Medicom Self-seal Pouch	133x413 mm	88017-4	1.20
Medicom Self-seal Pouch	190x356 mm	88030-4	1.46
Medicom Self-seal Pouch	191x388 mm	88022-4	1.57
Medicom Self-seal Pouch	203x356 mm	88023-4	1.55
Medicom Self-seal Pouch	203x464 mm	88024-4	1.95
Medicom Self-seal Pouch	229x407 mm	88028-4	1.94
Medicom Self-seal Pouch	254x381 mm	88035-4	1.99
Medicom Self-seal Pouch	267x457 mm	88029-4	2.38

Medicom Self-seal Pouch	305x457 mm	88040-4	2.59
Medicom Self-seal Pouch	305x515 mm	88032-4	2.76
Medicom Self-seal Pouch	330x533 mm	88034-4	2.92
Medicom Self-seal Pouch	415x636 mm	88038-4	2.98
Medicom Self-seal Pouch	381x727 mm	88090-4	2.90
Medicom Heat Seal Pouch	89x159 mm	870010	0.27
Medicom Heat seal pouch	89x254 mm	870020	0.50
Medicom Heat Seal Pouch	89x584 mm	870040	1.23
Medicom Heat Seal Pouch	133x279 mm	870060	0.87
Medicom Heat Seal Pouch	133x381 mm	870070	1.20
Medicom Heat Seal Pouch	152x279 mm	870100	1.00
Medicom Heat Seal Pouch	152x406 mm	870110	1.44
Medicom Heat Seal Pouch	191x356 mm	870140	1.57
Medicom Heat Seal Pouch	203x432 mm	870160	1.95
Medicom Heat Seal Pouch	203x635 mm	870170	2.56
Medicom Heat Seal Pouch	305x483 mm	870200	2.76
Medicom Heat Seal Pouch	415x603mm	870210	2.98
Medicom Heat seal pouch	457x559mm	870220	2.96
Medicom Flat Reel	50mmx30.5M	9510	0.26
Medicom Flat Reel	75mmx30.5M	9520	0.56
Medicom Flat Reel	100mmx30.5M	9530	0.84
Medicom Flat Reel	150mmx30.5M	9540	1.38
Medicom Flat Reel	200mmx30.5M	9550	1.88
Medicom Flat Reel	250mm x 30.5M	9560	2.35

Table 5-2. The model numbers of Medicom Sterilization Pouch and Reel

(Medical grade paper 60g+laminated film 52μm: Type, Model and Dimension and Max. Load)

Pouch of Combination B: Medical grade paper 60g+laminated film 52μm			
Type	Dimension	Model	Max. Load (lb.)
Medicom Self-seal Pouch	57x127 mm	881010	0.03
Medicom Self-seal Pouch	89x159 mm	881030	0.20
Medicom Self-seal Pouch	89x254 mm	881050	0.44
Medicom Self-seal Pouch	89x264 mm	881060	0.44
Medicom Self-seal Pouch	89x594 mm	881100	1.17
Medicom Self-seal Pouch	89x695 mm	881110	1.38
Medicom Self-seal Pouch	133x279 mm	881140	0.79
Medicom Self-seal Pouch	133x289 mm	881150	0.79
Medicom Self-seal Pouch	133x340 mm	881180	0.96
Medicom Self-seal Pouch	127x416 mm	881200	1.14
Medicom Self-seal Pouch	140x356 mm	881210	1.09
Medicom Self-seal Pouch	152x746 mm	881220	2.28
Medicom Self-seal Pouch	190x356 mm	881230	1.46
Medicom Self-seal Pouch	190x365 mm	881240	1.46
Medicom Self-seal Pouch	203x441 mm	881280	1.85
Medicom Self-seal Pouch	203x797 mm	881290	2.83
Medicom Self-seal Pouch	267x457 mm	881320	2.38
Medicom Self-seal Pouch	305x406 mm	881330	2.40
Medicom Self-seal Pouch	305x416 mm	881340	2.40
Medicom Self-seal Pouch	305x457 mm	881350	2.59
Medicom Self-seal Pouch	305x492 mm	881370	2.68

Medicom Self-seal Pouch	350x483 mm	881390	2.84
Medicom Self-seal Pouch	381x635 mm	881400	3.06
Medicom Self-seal Pouch	381x727 mm	881410	2.90
Medicom Heat Seal Pouch	89x159mm	871010	0.27
Medicom Heat Seal Pouch	89x559 mm	871030	1.17
Medicom Heat Seal Pouch	102x203 mm	871050	0.45
Medicom Heat Seal Pouch	127x381 mm	871080	1.14
Medicom Heat Seal Pouch	152x254 mm	871090	0.91
Medicom Heat Seal Pouch	152x559 mm	871120	1.90
Medicom Heat Seal Pouch	190x330 mm	871130	1.46
Medicom Heat Seal Pouch	203x406 mm	871150	1.85
Medicom Heat Seal Pouch	305x381 mm	871180	2.40
Medicom Heat Seal Pouch	305x457 mm	871190	2.68
Medicom Heat Seal Pouch	457x559 mm	871220	2.96
Medicom Flat Reel	50mm x 30.5M	951010	0.26
Medicom Flat Reel	75mm x 30.5M	951020	0.56
Medicom Flat Reel	75mm x 200M	951070	0.56
Medicom Flat Reel	100mm x 30.5M	951030	0.84
Medicom Flat Reel	100mm x 200M	951080	0.84
Medicom Flat Reel	150mm x 30.5M	951040	1.38
Medicom Flat Reel	150mm x 200M	951090	1.38
Medicom Flat Reel	200mm x 30.5M	951050	1.88
Medicom Flat Reel	200mm x 200M	951091	1.88
Medicom Flat Reel	250mm x 30.5M	951060	2.35
Medicom Flat Reel	250mm x 200M	951092	2.35

Table 5-3. The model numbers of Medicom Sterilization Pouch and Reel

(Medical grade paper 70g+laminated film 52μm: Type, Model and Dimension and Max. Load)

Pouch of Combination C: Medical grade paper 70g+laminated film 52μm			
Type	Dimension	Model	Max. Load (lb.)
Medicom Self-seal Pouch	57x127mm	882010	0.03
Medicom Self-seal Pouch	89x159 mm	882030	0.20
Medicom Self-seal Pouch	89x254 mm	882050	0.44
Medicom Self-seal Pouch	89x264 mm	882060	0.44
Medicom Self-seal Pouch	89x594 mm	882100	1.17
Medicom Self-seal Pouch	89x695 mm	882110	1.38
Medicom Self-seal Pouch	133x279mm	882140	0.79
Medicom Self-seal Pouch	133x289 mm	882150	0.79
Medicom Self-seal Pouch	133x340 mm	882180	0.96
Medicom Self-seal Pouch	127x416 mm	882200	1.14
Medicom Self-seal Pouch	140x356 mm	882210	1.09
Medicom Self-seal Pouch	152x746 mm	882220	2.28
Medicom Self-seal Pouch	190x356 mm	882230	1.46
Medicom Self-seal Pouch	190x365 mm	882240	1.46
Medicom Self-seal Pouch	203x441 mm	882280	1.85
Medicom Self-seal Pouch	203x797 mm	882290	2.82
Medicom Self-seal Pouch	267x457mm	882320	2.38
Medicom Self-seal Pouch	305x406 mm	882330	2.40
Medicom Self-seal Pouch	305x416mm	882340	2.40
Medicom Self-seal Pouch	305x457mm	882350	2.59
Medicom Self-seal Pouch	305x492 mm	882370	2.68

Medicom Self-seal Pouch	350x483 mm	882390	2.84
Medicom Self-seal Pouch	381x635 mm	882400	3.06
Medicom Self-seal Pouch	381x727 mm	882410	2.90
Medicom Heat Seal Pouch	89x159mm	872010	0.27
Medicom Heat Seal Pouch	89x559 mm	872030	1.17
Medicom Heat Seal Pouch	102x203 mm	872050	0.45
Medicom Heat Seal Pouch	127x381 mm	872080	1.14
Medicom Heat Seal Pouch	152x254 mm	872090	0.91
Medicom Heat Seal Pouch	152x559 mm	872120	1.90
Medicom Heat Seal Pouch	190x330 mm	872130	1.46
Medicom Heat Seal Pouch	203x406 mm	872150	1.85
Medicom Heat Seal Pouch	305x381 mm	872180	2.40
Medicom Heat Seal Pouch	305x457 mm	872190	2.68
Medicom Heat Seal Pouch	457x559 mm	872220	2.96
Medicom Flat Reel	50mm x 30.5M	952010	0.26
Medicom Flat Reel	75mm x 30.5M	952020	0.56
Medicom Flat Reel	75mm x 200M	952070	0.56
Medicom Flat Reel	100mm x 30.5M	952030	0.84
Medicom Flat Reel	100mm x 200M	952080	0.84
Medicom Flat Reel	150mm x 30.5M	952040	1.38
Medicom Flat Reel	150mm x 200M	952090	1.38
Medicom Flat Reel	200mm x 30.5M	952050	1.88
Medicom Flat Reel	200mm x 200M	952100	1.88
Medicom Flat Reel	250mm x 30.5M	952060	2.35
Medicom Flat Reel	250mm x 200M	952110	2.35

K243431 - 510 (K) Summary

Submitter's Information

Name:	Medicom Asia-Pacific Holdings Ltd. Taiwan Branch.
Address:	No. 11, Sec. 2, Ligong 1st Rd, Wujie Township, Yilan County 26841, Taiwan
Establishment Registration Number:	3008132392
Contact:	Henry Chu General Manager TEL: +886-3-990-9100 email: hchu@medicom-taiwan.com email: sales@medicom-taiwan.com
Date Prepared:	February 20, 2025

Device Name

Trade Name:	Medicom Sterilization Pouch and Reel
Common/usual Name:	Medicom Sterilization Pouch and Reel
Device Classification Names:	1) Wrap, Sterilization. 2) Indicator, Physical/Chemical Sterilization Process
Panel:	General Hospital
Classification Product Code: Subsequent Product Code:	1) FRG 2) JOJ
Device Classification:	Class II
Regulation Number:	1) 21 CFR 880.6850 2) 21 CFR 880.2800

Predicate Devices

The predicate device [510(k) Notification K153540, cleared August 4, 2016] is the Safe Secure Sterilization Pouch with Steam and Ethylene Oxide Process Indicators.

Indications for Use

The Medicom Sterilization Pouch and Reel are intended to provide health care workers with an effective method to enclose devices, and they can use Single Pouch or Double Pouches intended for sterilization in the Steam or via Ethylene Oxide (EO).
The recommended sterilization cycles are as follows:

- Gravity steam at 121°C (250°F) for 30 minutes; Drying time of 25 minutes.
- Pre-vacuum steam at 132°C (270°F) for 4 minutes; Drying time of 20 minutes.
- Pre-vacuum steam at 134°C (273°F) for 4 minutes; Drying time of 20 minutes.
- Ethylene Oxide (EO) with a concentration of 600 mg/L at 50°C (122°F) and 60% to 85% relative humidity for 120 minutes. Single Pouch: Aeration time of 5 days at 25°C (77°F). Double Pouches: Aeration time of 3 days at 25°C (77°F).

Furthermore, there are 3 thicknesses for health care workers to choose from as follows:

- Pouch of Combination A: Medical grade paper 60g+laminated film 44μm
- Pouch of Combination B: Medical grade paper 60g+laminated film 52μm
- Pouch of Combination C: Medical grade paper 70g+laminated film 52μm

The Medicom Sterilization Pouch and Reel which are made with Paper maintains the sterility of the enclosed devices for up to 1 year post Steam or EO gas sterilization, and before sterilization has a maximum shelf life of 3 years from the date of manufacture. The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process.

The following table (Table 5-1 to Table 5-3) lists the model numbers of the Medicom Sterilization Pouch and Reel by type, model, dimensions, and max. load (lbs.):

Table 5-1. The model numbers of Medicom Sterilization Pouch and Reel

(Medical grade paper 60g+laminated film 44μm: Type, Model and Dimension and Max. Load)

Pouch of Combination A: Medical grade paper 60g+laminated film 44μm			
Type	Dimension	Model	Max. Load (lb.)
Medicom Self-seal Pouch	57x127 mm	88015-4	0.03
Medicom Self-seal Pouch	70x254 mm	88000-4	0.32
Medicom Self-seal Pouch	89x159 mm	88005-4	0.20
Medicom Self-seal Pouch	89x191 mm	88001-4	0.27
Medicom Self-seal Pouch	89x254 mm	88010-4	0.44
Medicom Self-seal Pouch	89x286 mm	88003-4	0.50
Medicom Self-seal Pouch	83x330 mm	88004-4	0.57
Medicom Self-seal Pouch	89x617 mm	88006-4	1.23
Medicom Self-seal Pouch	108x305 mm	88009-4	0.70
Medicom Self-seal Pouch	133x190 mm	88011-4	0.48
Medicom Self-seal Pouch	133x279 mm	88025-4	0.79
Medicom Self-seal Pouch	133x311 mm	88013-4	0.87
Medicom Self-seal Pouch	133x330 mm	88014-4	0.96
Medicom Self-seal Pouch	133x413 mm	88017-4	1.20
Medicom Self-seal Pouch	190x356 mm	88030-4	1.46
Medicom Self-seal Pouch	191x388 mm	88022-4	1.57
Medicom Self-seal Pouch	203x356 mm	88023-4	1.55
Medicom Self-seal Pouch	203x464 mm	88024-4	1.95
Medicom Self-seal Pouch	229x407 mm	88028-4	1.94
Medicom Self-seal Pouch	254x381 mm	88035-4	1.99
Medicom Self-seal Pouch	267x457 mm	88029-4	2.38

Medicom Self-seal Pouch	305x457 mm	88040-4	2.59
Medicom Self-seal Pouch	305x515 mm	88032-4	2.76
Medicom Self-seal Pouch	330x533 mm	88034-4	2.92
Medicom Self-seal Pouch	415x636 mm	88038-4	2.98
Medicom Self-seal Pouch	381x727 mm	88090-4	2.90
Medicom Heat Seal Pouch	89x159 mm	870010	0.27
Medicom Heat seal pouch	89x254 mm	870020	0.50
Medicom Heat Seal Pouch	89x584 mm	870040	1.23
Medicom Heat Seal Pouch	133x279 mm	870060	0.87
Medicom Heat Seal Pouch	133x381 mm	870070	1.20
Medicom Heat Seal Pouch	152x279 mm	870100	1.00
Medicom Heat Seal Pouch	152x406 mm	870110	1.44
Medicom Heat Seal Pouch	191x356 mm	870140	1.57
Medicom Heat Seal Pouch	203x432 mm	870160	1.95
Medicom Heat Seal Pouch	203x635 mm	870170	2.56
Medicom Heat Seal Pouch	305x483 mm	870200	2.76
Medicom Heat Seal Pouch	415x603mm	870210	2.98
Medicom Heat seal pouch	457x559mm	870220	2.96
Medicom Flat Reel	50mmx30.5M	9510	0.26
Medicom Flat Reel	75mmx30.5M	9520	0.56
Medicom Flat Reel	100mmx30.5M	9530	0.84
Medicom Flat Reel	150mmx30.5M	9540	1.38
Medicom Flat Reel	200mmx30.5M	9550	1.88
Medicom Flat Reel	250mm x 30.5M	9560	2.35

Table 5-2. The model numbers of Medicom Sterilization Pouch and Reel

(Medical grade paper 60g+laminated film 52μm: Type, Model and Dimension and Max. Load)

Pouch of Combination B: Medical grade paper 60g+laminated film 52μm			
Type	Dimension	Model	Max. Load (lb.)
Medicom Self-seal Pouch	57x127 mm	881010	0.03
Medicom Self-seal Pouch	89x159 mm	881030	0.20
Medicom Self-seal Pouch	89x254 mm	881050	0.44
Medicom Self-seal Pouch	89x264 mm	881060	0.44
Medicom Self-seal Pouch	89x594 mm	881100	1.17
Medicom Self-seal Pouch	89x695 mm	881110	1.38
Medicom Self-seal Pouch	133x279 mm	881140	0.79
Medicom Self-seal Pouch	133x289 mm	881150	0.79
Medicom Self-seal Pouch	133x340 mm	881180	0.96
Medicom Self-seal Pouch	127x416 mm	881200	1.14
Medicom Self-seal Pouch	140x356 mm	881210	1.09
Medicom Self-seal Pouch	152x746 mm	881220	2.28
Medicom Self-seal Pouch	190x356 mm	881230	1.46
Medicom Self-seal Pouch	190x365 mm	881240	1.46
Medicom Self-seal Pouch	203x441 mm	881280	1.85
Medicom Self-seal Pouch	203x797 mm	881290	2.83
Medicom Self-seal Pouch	267x457 mm	881320	2.38
Medicom Self-seal Pouch	305x406 mm	881330	2.40
Medicom Self-seal Pouch	305x416 mm	881340	2.40
Medicom Self-seal Pouch	305x457 mm	881350	2.59
Medicom Self-seal Pouch	305x492 mm	881370	2.68

Medicom Self-seal Pouch	350x483 mm	881390	2.84
Medicom Self-seal Pouch	381x635 mm	881400	3.06
Medicom Self-seal Pouch	381x727 mm	881410	2.90
Medicom Heat Seal Pouch	89x159mm	871010	0.27
Medicom Heat Seal Pouch	89x559 mm	871030	1.17
Medicom Heat Seal Pouch	102x203 mm	871050	0.45
Medicom Heat Seal Pouch	127x381 mm	871080	1.14
Medicom Heat Seal Pouch	152x254 mm	871090	0.91
Medicom Heat Seal Pouch	152x559 mm	871120	1.90
Medicom Heat Seal Pouch	190x330 mm	871130	1.46
Medicom Heat Seal Pouch	203x406 mm	871150	1.85
Medicom Heat Seal Pouch	305x381 mm	871180	2.40
Medicom Heat Seal Pouch	305x457 mm	871190	2.68
Medicom Heat Seal Pouch	457x559 mm	871220	2.96
Medicom Flat Reel	50mm x 30.5M	951010	0.26
Medicom Flat Reel	75mm x 30.5M	951020	0.56
Medicom Flat Reel	75mm x 200M	951070	0.56
Medicom Flat Reel	100mm x 30.5M	951030	0.84
Medicom Flat Reel	100mm x 200M	951080	0.84
Medicom Flat Reel	150mm x 30.5M	951040	1.38
Medicom Flat Reel	150mm x 200M	951090	1.38
Medicom Flat Reel	200mm x 30.5M	951050	1.88
Medicom Flat Reel	200mm x 200M	951091	1.88
Medicom Flat Reel	250mm x 30.5M	951060	2.35
Medicom Flat Reel	250mm x 200M	951092	2.35

Table 5-3. The model numbers of Medicom Sterilization Pouch and Reel

(Medical grade paper 70g+laminated film 52μm: Type, Model and Dimension and Max. Load)

Pouch of Combination C: Medical grade paper 70g+laminated film 52μm			
Type	Dimension	Model	Max. Load (lb.)
Medicom Self-seal Pouch	57x127mm	882010	0.03
Medicom Self-seal Pouch	89x159 mm	882030	0.20
Medicom Self-seal Pouch	89x254 mm	882050	0.44
Medicom Self-seal Pouch	89x264 mm	882060	0.44
Medicom Self-seal Pouch	89x594 mm	882100	1.17
Medicom Self-seal Pouch	89x695 mm	882110	1.38
Medicom Self-seal Pouch	133x279mm	882140	0.79
Medicom Self-seal Pouch	133x289 mm	882150	0.79
Medicom Self-seal Pouch	133x340 mm	882180	0.96
Medicom Self-seal Pouch	127x416 mm	882200	1.14
Medicom Self-seal Pouch	140x356 mm	882210	1.09
Medicom Self-seal Pouch	152x746 mm	882220	2.28
Medicom Self-seal Pouch	190x356 mm	882230	1.46
Medicom Self-seal Pouch	190x365 mm	882240	1.46
Medicom Self-seal Pouch	203x441 mm	882280	1.85
Medicom Self-seal Pouch	203x797 mm	882290	2.82
Medicom Self-seal Pouch	267x457mm	882320	2.38
Medicom Self-seal Pouch	305x406 mm	882330	2.40
Medicom Self-seal Pouch	305x416mm	882340	2.40
Medicom Self-seal Pouch	305x457mm	882350	2.59
Medicom Self-seal Pouch	305x492 mm	882370	2.68

Medicom Self-seal Pouch	350x483 mm	882390	2.84
Medicom Self-seal Pouch	381x635 mm	882400	3.06
Medicom Self-seal Pouch	381x727 mm	882410	2.90
Medicom Heat Seal Pouch	89x159mm	872010	0.27
Medicom Heat Seal Pouch	89x559 mm	872030	1.17
Medicom Heat Seal Pouch	102x203 mm	872050	0.45
Medicom Heat Seal Pouch	127x381 mm	872080	1.14
Medicom Heat Seal Pouch	152x254 mm	872090	0.91
Medicom Heat Seal Pouch	152x559 mm	872120	1.90
Medicom Heat Seal Pouch	190x330 mm	872130	1.46
Medicom Heat Seal Pouch	203x406 mm	872150	1.85
Medicom Heat Seal Pouch	305x381 mm	872180	2.40
Medicom Heat Seal Pouch	305x457 mm	872190	2.68
Medicom Heat Seal Pouch	457x559 mm	872220	2.96
Medicom Flat Reel	50mm x 30.5M	952010	0.26
Medicom Flat Reel	75mm x 30.5M	952020	0.56
Medicom Flat Reel	75mm x 200M	952070	0.56
Medicom Flat Reel	100mm x 30.5M	952030	0.84
Medicom Flat Reel	100mm x 200M	952080	0.84
Medicom Flat Reel	150mm x 30.5M	952040	1.38
Medicom Flat Reel	150mm x 200M	952090	1.38
Medicom Flat Reel	200mm x 30.5M	952050	1.88
Medicom Flat Reel	200mm x 200M	952100	1.88
Medicom Flat Reel	250mm x 30.5M	952060	2.35
Medicom Flat Reel	250mm x 200M	952110	2.35

Device Description

The medical devices are inserted into the Medicom Sterilization Pouch and Reel, sealed, and then sterilized in the Sterilization System. After completion of the sterilization process, the Pouch/Reel maintains the sterility of the enclosed medical devices until the seal is opened. And they can use Single Pouch or Double Pouches intended for sterilization in the Steam or via Ethylene Oxide (EO).

The device is intended to allow the sterilization of enclosed devices and maintain sterility for the enclosed devices until used up to 1-year post-steam or EO gas sterilization.

The Self-seal pouch permits the sealing of the pouch without heat-sealing equipment, while the heat-sealed pouches and reels are heat-sealed before processing in the steam/or EO Sterilization.
The chemical indicators printed on the "medical grade paper" will exhibit color change after the pouch is exposed to steam or ethylene oxide gas. The “Medicom Sterilization Pouch and Reel” is printed with dual chemical indicators that the color change from Red/Pink to Cocoa when exposed to Steam, and the color changes from Blue to Golden Yellow /Brown, when exposed to EO gas.

The Chemical Indicator offers an additional way to verify processing in the sterilization cycle. The Chemical Indicator should be used in addition to, but not in place of, the biological indicator. The Chemical Indicators do not signify sterilization; they only indicate that the indicator has been exposed to Steam/or EO gas.
Furthermore, there are 3 thicknesses with dimensions for health care workers to choose from as follows:

- Pouch of Combination A: Medical grade paper 60g+laminated film 44μm
  Dimensions of 880 series: W: 57mm ~ 415mm; L: 127mm~727mm
  Dimensions of 870 series: W: 89mm ~ 457mm; L: 159mm~635mm
  Dimensions of 95 series: W: 50mm ~ 250mm; L: ~30.5M
- Pouch of Combination B: Medical grade paper 60g+laminated film 52μm
  Dimensions of 881 series: W: 57mm ~ 381mm; L: 127mm~797mm
  Dimensions of 871 series: W: 89mm ~ 457mm; L: 159mm~559mm
  Dimensions of 951 series: W: 50mm ~ 250mm; L: ~200M
- Pouch of Combination C: Medical grade paper 70g+laminated film 52μm
  Dimensions of 882 series: W: 57mm ~ 381mm; L: 127mm~797mm
  Dimensions of 872 series: W: 89mm ~ 457mm; L: 159mm~559mm
  Dimensions of 952 series: W: 50mm ~ 250mm; L: ~200M

Description of Comparison and Substantial Equivalence

A summary of the technological characteristics of the device subject of this premarket notification in comparison to those of the predicate devices is included in **Table 5-4**

Table 5-4. Summary of the Proposed and Predicate Devices Technological Characteristics

Feature	Proposed device	Predicate device	Comparison
Device name	**Medicom Sterilization Pouch and Reel**	**Safe Secure Sterilization Pouch with Steam and Ethylene Oxide (K153540)**	
Material Composition	• Medical Grade Paper, CPP, PET, PU adhesive, EO and Steam Process Indicator, Print Ink., Double-side adhesive tape	Medical Grade Paper, CPP, PET, PU adhesive, EO and Steam Process Indicator, Print Ink.	Same.
Intended use	The Medicom Sterilization Pouch and Reel are intended to provide health care workers with an effective method to enclose devices, and they can use Single Pouch or Double Pouches intended for sterilization in the Steam or via Ethylene Oxide (EO). The recommended sterilization cycles are as follows: • Gravity steam at 121°C (250°F) for 30 minutes; Drying time of 25 minutes. • Pre-vacuum steam at 132°C (270°F) for 4 minutes; Drying time of 20 minutes. • Pre-vacuum steam at 134°C (273°F) for 4 minutes; Drying time of 20 minutes. • Ethylene Oxide (EO) with a concentration of 600 mg/L at 50°C (122°F) and 60% to 85% relative humidity for 120 minutes. Single Pouch: Aeration time of 5 days at 25°C (77°F). Double Pouches: Aeration time of 3 days at 25°C (77°F). Furthermore, there are 3 thicknesses for health care workers to choose from as follows: • Pouch of Combination A: Medical grade paper 60g+laminated film 44μm • Pouch of Combination B: Medical grade paper 60g+laminated film 52μm • Pouch of Combination C: Medical grade paper 70g+laminated film 52μm The Medicom Sterilization Pouch and Reel which are made with Paper maintains the sterility of the enclosed devices for up to 1 year post Steam or EO gas sterilization, and before sterilization has a maximum shelf life of 3 years from the date of manufacture. The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process.	Safe Secure Paper Sterilization Pouches and Rolls are intended to be used to enclose another medical device, in a single or double pouch configuration, that is to be sterilized by a health care provider using: • Gravity Steam at 121°C (250°F) for 30 minutes; 25 minutes dry time • Pre-vacuum Steam at 132°C (270°F) for 4 minutes; 20 minutes dry time • Pre-vacuum Steam at 134°C (273°F) for 3 minutes; 20 minutes dry time • Pre-vacuum steam at 135°C (275°F) for 3 minutes; 16 minutes dry time • Ethylene Oxide (EO) with a concentration of 735 mg/L at 55°C (131°F) and 50% to 80% relative humidity for 60 minutes. Aeration time of 8 hours at 60ºC (140°F). The device is not intended and has not been validated for sterilization of devices that contain lumens. The external chemical indicators on the pouches/rolls are intended to demonstrate that the device has been exposed to the Steam or EO sterilization process and to distinguish between processed and unprocessed devices. The chemical indicators change from green to purple after exposure to steam and from yellow to brown after exposure to ethylene oxide.	Similarly, the Steam sterilization of the proposed device increase by one cycle (Pre-vacuum 132°C/ 4 min). The proposed device is available in 3 thicknesses for health care workers to choose.

Table 5-4. (Continued) Summary of the Proposed and Predicate Devices Technological Characteristics

Feature	Proposed device: Medicom Sterilization Pouch and Reel	Predicate device: Safe Secure Sterilization Pouch with Steam and Ethylene Oxide (K153540)	Comparison
Pouch Types	**Combination A: Medical grade paper 60g+laminated film 44µm** Type: • Self-seal Pouch • Heat Seal Pouch • Flat Reel **Combination B: Medical grade paper 60g+laminated film 52µm** Type: • Self-seal Pouch • Heat Seal Pouch • Flat Reel **Combination C: Medical grade paper 70g+laminated film 52µm** Type: • Self-seal Pouch • Heat Seal Pouch • Flat Reel	Type: • Pouch paper heat seal • Tubing paper roll • Pouch multiple • Pouch paper self-seal	Similar, the predicate device has 1 more type "Pouch multiple".
Device models (Configurations/Dimensions)	**Combination A: Medical grade paper 60g+laminated film 44µm Self-seal Pouch** Size: W: 57 mm ~ 415mm, L: 127 mm ~ 727mm Model: 880	**Pouch paper self-seal** Size: W: 89 mm ~ 330 mm, L:245 mm ~ 671mm Model: ABSSP10	Similar
	Heat Seal Pouch Size: W: 89 mm ~ 457mm, L: 159 mm ~ 635mm Model: 870	**Pouch paper heat seal** Size: W: 76 mm ~ 457mm, L: 203 mm ~ 559mm Model: ABHSP10	Similar
	Flat Reel Size: W: 50 mm ~ 250 mm, L: ~ 30.5 M Model: 95	**Tubing paper width 100FT Roll** Size: W: 51mm ~ 305 mm, L: ~ 30.5 M Model: ABHSP11	Similar
	Combination B: Medical grade paper 60g+laminated film 52µm Self-seal Pouch Size: W: 57 mm ~ 381mm, L: 127 mm ~ 797mm Model: 881	**N/A**	The proposed device is available in 3 thicknesses.
	Heat Seal Pouch Size: W: 89 mm ~ 457mm, L: 159 mm ~ 559mm Model: 871	**N/A**	The proposed device is available in 3 thicknesses.
	Flat Reel Size: W: 50 mm ~ 250 mm, L: ~ 200 M Model: 951	**N/A**	The proposed device is available in 3 thicknesses.

	Combination C: Medical grade paper 70g + laminated film 52μm Self-seal Pouch Size: W: 57 mm ~ 381mm, L: 127 mm ~ 797mm — Model: 882	**N/A**	The proposed device is available in 3 thicknesses.
	Heat Seal Pouch Size: W: 89 mm ~ 457mm, L: 159 mm ~ 559mm — Model: 872	**N/A**	The proposed device is available in 3 thicknesses.
	Flat Reel Size: W: 50 mm ~ 250 mm, L: ~ 200 M — Model: 952	**N/A**	The proposed device is available in 3 thicknesses.
Steam Sterilization cycle	The recommended steam sterilization parameters are as follows: The recommended sterilization cycles are as follows: • Gravity steam at 121°C (250°F) for 30 minutes; Drying time of 25 minutes. • Pre-vacuum steam at 132°C (270°F) for 4 minutes; Drying time of 20 minutes. • Pre-vacuum steam at 134°C (273°F) for 4 minutes; Drying time of 20 minutes.	The recommended steam sterilization parameters are as follows: • Gravity steam at 121°C (250°F) for 30 minutes; 25 minutes dry time • Pre-vacuum steam at 132°C (270°F) for 4 minutes; 20 minutes dry time • Pre-vacuum steam at 134°C (273°F) for 3 minutes; 20 minutes dry time • Pre-vacuum steam at 135°C (275°F) for 3 minutes; 16 minutes dry time	Similarly
EO gas Sterilization cycle	The recommended EO sterilization parameters is as follows: • Ethylene Oxide (EO) with a concentration of 600 mg/L at 50°C (122°F) and 60% to 85% relative humidity for 120 minutes. Single Pouch: Aeration time of 5 days at 25°C (77°F). Double Pouches: Aeration time of 3 days at 25°C (77°F).	The recommended EO sterilization parameters is as follows: • Ethylene Oxide (EO) with a concentration of 735 mg/L at 55°C (131°F) and 50% to 80% relative humidity for 60 minutes. Aeration time of 8 hours at 60°C (140°F).	Similarly
Design Features	**Self-seal Pouch:** These pouches are made of medical grade paper and plastic film with a double-side adhesive tape at the flap. The pouch is formed by heat-sealing on three sides, leaving the fourth side open allowing the users to place devices for sterilization. The double-side adhesive tape is comprising of a tissue strip coated with acrylic adhesives and it is protected via a laminated PE/paper/PE release paper which will firstly be removed allowing the sealing of the fourth side. The medical grade paper conforms to recognized material standards and can be sterilized by steam or ethylene oxide gas. The Process Indicators Ink printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam or ethylene oxide gas. **Heat Seal Pouch:** These pouches has the same components with the Self-seal Pouch, except the forth side is left opened instead of an adhesive strip and will be heat-sealed when using. **Flat Reel:** These reel made from a medical grade paper and plastic film that are heat sealed on opposite two sides. It will be cut into the suitable length and the opened sides will be heat-sealed. The indicators printed on the medical grade paper are the same with the Self-seal Pouch.	**Pouch paper self-seal:** These pouches are made from a medical grade plastic film that is heat sealed on three sides. The forth side has an adhesive strip that is used to seal the pouch. Release paper used in the pouch is a laminated sheet with composing structure of PE/paper/PE. It is a strip to cover the adhesive area and is released before seal the pouch. The medical grade paper conforms to recognized material standards and can be sterilized by steam or ethylene oxide gas. The Process Indicators Ink printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam or ethylene oxide gas. **Pouch paper Heat Seal:** These pouches has the same components with the Pouch paper self-seal, except the forth side is left opened instead of an adhesive strip and will be heat-sealed when using. **Tubing paper roll:** These reel made from a medical grade paper and plastic film that are heat sealed on opposite two sides. It will be cut into the suitable length and the opened sides will be heat-sealed. The indicators printed on the medical grade paper are the same with the Pouch paper self-seal.	Similarly

Table 5-4. (Continued) Summary of the Proposed and Predicate Devices Technological Characteristics

Feature / **Performance Testing**		Proposed Device: Medicom Sterilization Pouch and Reel	Predicate Devices: Safe Secure Sterilization Pouch with Steam and Ethylene Oxide (K153540)	**Comparison**
Sterilant Penetration	**Half-Cycle Efficacy**	The test meet the requirement of SAL 10^{-6}	The test meet the requirement of SAL 10^{-6}	Same
	Chemical Indicator (CI) Functionality and Endpoint	The sterilant penetrated through the pouch configuration and affected the CI color change to the endpoint color	The sterilant penetrated through the pouch configuration and affected the CI color change to the endpoint color	Same
	Device Design of Steam CI	The color of Chemical Indicator changes from Red/Pink to Cocoa, when exposed to Steam.	The color of Chemical Indicator changes from green to purple, when exposed to Steam.	Similar
	Device Design of EO gas CI	The color changes from Blue to Golden Yellow /Brown, when exposed to EO gas.	The color changes from yellow to brown, when exposed to EO gas.	Similar
Package Integrity (Physical Properties)	**Thickness Variations (mm)** *ASTM F 2251 ; ISO 534*	Passed	Passed	Same
	Tensile strength of paper* (kN/m; N/15mm) *ISO 1924-2*	Passed	Passed	Same
	Air permeance of paper* (µm /(Pa · s)) *ISO 5636-3*	Passed	Passed	Same
	Total Lead (Pb) Content Test	Passed (N.D.)	Not tested	Better
	Burst Strength (kPa**)** *ASTM F1140 ; ISO 11607-1*	Passed	Passed	Same
	Bubble Leak Test *ASTM D 3078 ; ASTM-F 2096*	Passed	Passed	Same
	Seal Peel Test (N/15mm) *ASTM F88/F88M ; ISO 11607-1*	Passed	Passed	Same
	Visual Inspection (Seal Integrity) *ASTM F1886/F1886M;*	Passed	Passed	Same
	Dye penetration Test *ASTM F 1929 ;ISO 11607-1*	Passed	Passed	Same
	Microbial Barrier Test *DIN 58953-6 ;or ASTM F 1608*	Passed	Passed	Same
	Toxicological Properties (Biocompatibility Test) *ANSI/AAMI/ISO 10993-10*	Passed	Passed	Same
	Accelerated Aging Test *(Durability) ASTM F 1980 ; ISO 11607-1*	Passed	Passed	Same
End Point / Post Processing Color Stability	**After Steam sterilization**	1 Year	6 months	Similar
	After EO sterilization	1 Year	24 months	Similar
Shelf Life	**Chemical Indicator (CI) Functionality**	3 Years	5 Years	Similar
	Accelerated aging test	3 Years	5 Years	Similar

*Note: *the test items were performed on materials of the products; therefore, there is no specification requirements.*

Summary of Non-Clinical Testing

The Medicom Sterilization Pouch and Reel has the identical intended use and indication for use as the predicate devices. The subject device was compared to the predicate device by testing the Sterilant Penetration, Drying Time, Aeration, Biocompatibility, Package Integrity, Material Compatibility, Sterility Maintenance, and Chemical Indicator Efficacy.

The results of the Medicom Sterilization Pouch and Reel validation studies demonstrate that the sterilization pouches perform as intended. The results are summarized as following **Table 5-5**:

Table 5-5. Summary of Non-Clinical Testing

Test completed	Standards followed	Acceptance criteria	Results
Sterilant Penetration/ Drying Time/ Aeration	ANSI/AAMI/ISO 17665-1:2006/(R)2013	- Meet the requirement of SAL 10^{-6}, the test BI (the Steam processed): No bacterial growth -The weight difference before sterilization and after drying shall not exceed 0 %	Pass
	ANSI/AAMI/ISO TIR 17665-2:2009 (R2016)		
	AAMI / ANSI / ISO 11135:2014	Meet the requirement of SAL 10^{-6}, the test BI (the EO processed): No bacterial growth	Pass
	ISO 10993-7:2008 (R) 2012	EO ≤ 4mg ECH ≤ 9mg	Pass
Biocompatibility testing	ISO 10993-5 :2009	Grade level ≤ 2	Pass
	ISO 10993-10:2021	Sensitization rate ≤ 8 %	Pass
	ISO 10993-23:2021	Non-irritating: mean PII ≤ 0.4	Pass
Package Integrity/ Material Compatibility/ Sterility Maintenance	ANSI/AAMI/ISO 11607-1:2019-02		
	ISO 1924-2:2008	Machine direction (MD) ≥ 4.4 kN/m Cross direction (CD) ≥ 2.2 kN/m	Pass
	ISO 5636-3:2013	≥ 3.4 μm /Pa · s	Pass
	ASTM F 2251-13(2018)	Medical grade paper ≥ 78μm	Pass
	ASTM F1886/F1886M -16	No visual defects	Pass
	ASTM F1140/F1140M-13 (Reapproved 2020)	Self-seal pouches: ≥ 8.0 in. H_2O Heat Seal pouches: ≥ 8.0 in. H_2O Flat reels: ≥ 18.0 in. H_2O	Pass
	ASTM F1929-15	No leaks	Pass

Package Integrity/ Material Compatibility/ Sterility Maintenance	ASTM F88/F88M-21	• Post-steam /EO sterilization: ≥ 1.5N/15mm (≥ 0.57 lb_f/inch)	Pass
	ASTM F 1980-21	3-Year accelerated aging Incubation: Range of Actual Value: Temp: 55℃± 2℃, Relative humidity 50%± 5%	Pass
		1 Year accelerated aging Incubation: Range of Actual Value: Temp: 55℃± 2℃, Relative humidity 50%± 5%	
	ASTM F2096-11(Reapproved 2019)	No gross leaks	Pass
	ASTM F1608-21	LRV ≥ 1.0	Pass
Chemical Indicator Efficacy testing (Type 1 Indicators)	AAMI/ANSI/ISO 11140-1:2014	• Change the color: (**Steam**) · 121℃ / 2.0 min & 132℃/ 0.3 min & 134 ℃/ 0.3 min : Unacceptable result (Color: Red/Pink) · 121℃/10.0 min & 132℃/ 2.0 min & 134 ℃/ 2.0 min : Acceptable result (Color: Cocoa) · Dry heat 140℃/30 min: Unacceptable result (Color: Red/Pink) Note: The color of CI changes from Red/Pink to Cocoa, when exposed to Steam.	Pass
		• Change the color: (**EO gas**) · EO gas Treat / 2 min: Unacceptable result (Color: Blue) · EO gas Treat /20 min: Acceptable result (Color: Golden Yellow /Brown) · Absence of EO gas / 90 min: Unacceptable result (Color: Blue) Note: The color of CI changes from Blue to Golden Yellow /Brown, when exposed to EO gas.	Pass
		• Shelf life: Remain stable before use based on its shelf life for 3 years.	Pass
		• Maintain the endpoint stability: Maintain the endpoint stability of the color change for 1 year after being in the presence of the sterilant.	Pass
Total Lead (Pb) Test		Not Detected (N.D.)	Pass

CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that Medicom Sterilization Pouch and Reel is as safe, as effective, and performs as well as or better than the predicate K153540.