



Food and Drug Administration
10903 New Hampshire Avenue
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August 18, 2014

3M Health Care
Mr. Mark Burville
Regulatory Affairs Manager
3M Center, 2510 Conway Ave., Building 275-5W-06
St Paul, MN 55144

Re: K140330
Trade/Device Name: 3 M Steri-Drape Fabric Surgical Drapes
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: Class II
Product Code: KKK
Dated: July 14, 2014
Received: July 16, 2014

Dear Mr. Burville,

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. 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. Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General
Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K140330

Device Name

3M Steri-Drape Fabric Surgical Drapes

Indications for Use (Describe)

3M Steri-Drape Fabric Surgical Drapes are used to create a sterile field for surgical procedures. They are provided sterile and intended for external use only.

3M Steri-Drape non-sterile fabric drapes are provided to other manufacturers for further processing using ethylene oxide. 3M provides information on compatibility with ethylene oxide processing.

Non-sterile surgical drapes are sold to repackager or relabeler establishments for EtO sterilization according to ISO 11135-1:2007. Sterile surgical drapes are sold directly to end users after EtO sterilization validation to ISO 11135-1:2007.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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Table 1 – Product Catalog Numbers, Dimensions and Name/Descriptor

Catalog Number(s)	Dimensions	Name/Descriptor
1031	228cm · 90in (Width Top) 182cm · 72in (Width Bottom) 285cm · 112in (Length)	Laparoscopic Drape/Supine Position
1032	228cm · 90in (Width Top) 117cm · 46in (Length of Panel) 241cm · 95in (Length)	Laparoscopic Drape/Lithotomy Position
1034	152cm x 200cm 60in x 78in	Central Venous Catheter Drape
1078	196cm x 200cm No inches stated	Perineal Drape with Pouch
1079	195cm · 77in (Width Top) 117cm · 46in (Length of Panel) 179cm · 70in (Length)	Gynecologic Drape
1080	195cm · 77in (Width Top) 117cm · 46in (Length of Panel) 179cm · 70in (Length)	Gynecologic Drape
1081	152cm x 164cm Upper 60in x 64in 117cm / 46in Lower	TUR/Urological Drape
1082	235cm · 92in 300cm · 118 in	Abdominal Vaginal Drape
1084	86cm x 108cm 34in x 42in	Under Buttocks Drape with Pouch
1089	57cm x 66cm 22in x 26in	Utility Sheet (2)
1090	182cm x 228cm 72in x 90in	Femoral Angiography Drape
1092	57cm x 66cm 22in x 25in	Small Drape with Adhesive Aperture
1094	226cm x 320cm 90in x 126in	Arthroscopy Sheet with Pouch
1135	279cm x 183cm 110in x 72in 15cm x 13cm 5.9in x 5 in	Peripherally Inserted Central Catheter Drape
*1190NS	228cm x 330cm 89in x 130in	Femoral Angiography Drape
1191	229cm x 330cm 90in x 130in	Femoral Angiography Drape

Catalog Number(s)	Dimensions	Name/Descriptor
1192	152cm x 170cm 60in x 67in	Venous/Arterial Access Drape
1193	290cm x 345cm 114in x 136in	Angiography Drape
1194	292cm · 115in (Width Top) 228cm · 89in (Width Bottom) 304cm · 120in (Length)	Arthroscopy Sheet with Pouch
2065	195cm · 77in (Width Top) 271cm · 106in (Total Length)	Abdominoperineal Incise Drape
7964	254cm x 279cm 100in x 110in	Abdominoperineal Incise Drape- Lithotomy Position
7965	254cm · 100in (Width Top) 195cm · 76in (Width Bottom) 308cm · 121in (Length)	Cesarean Section Incise Sheet with Pouch
7966	254cm · 100in (Width Top) 195cm 76in (Width Bottom) 310cm · 122in (Length)	Cesarean Section Sheet with Aperture Pouch
9023	76cm x 170cm 29in x 67in	Perineal Aperture Drape
9026	6cm x 8cm (Aperture) 2.3in x 3.1in 55cm x 55cm 21in x 21in	Aperture Drape
9027	Part 1 50cm x 75cm 19in x 19in Part 2 50cm x 75cm 19in x 19in	Adjustable Aperture Drape
9027L	Part 1 75cm x 100cm 29in x 39in Part 2 75cm x 100cm 29in x 39in	Adjustable Adhesive Aperture Drape
9028	6cm x 8cm (Aperture) 2.3 in x 3.1 in 75cm x 75cm 29in x 29in	Adhesive Aperture Drape
9029	15 cm x 6 cm (Aperture) 6 in x 2 in 75cm x 75cm 29in x 29in	Adhesive Aperture Drape
9030	6cm x 8cm (Aperture) 2 in x 3in 152cm x 120cm 60in x 47in	Adhesive Aperture Drape

Catalog Number(s)	Dimensions	Name/Descriptor
9031	8cm x 6cm (Aperture) 3 in x 2 in 150cm x 183cm 59in x 72in	Adhesive Aperture Drape
*9033NS	150cm x 183cm 59in x 72in	Triangular Aperture Drape
9040	75cm x 114cm 29in x 44in	Leggings (2)
9040L (pair)	85cm x 130cm 33in x 51in	Legging Long
9041	35cm x 60cm 13.5in x 23.5in	Extremity Cover (S)
9042	35cm x 100cm 13.5in x 39in	Extremity Cover (L)
9043	7 cm x 70 cm (split) 2.5in x 25 in 152cm x 183cm 60in x 72in	Adhesive Split Sheet
9044	7cm x 70cm (split) 2.5in x 25 in 152cm x 250cm 60in x 98in	Adhesive Split Sheet
9045	20cm x 100cm (split) 7in x 39 in 228cm x 260cm 89.5in x 102in	Adhesive Split Sheet
9045R	20cm x 100cm (split) 7in x 39 in 228cm x 260cm 89.5in x 102in	Reinforced Adhesive Split Sheet
9046	183cm x 200cm 72in x 78in	Bilateral Adhesive Split Sheet
9046L	228cm x 260cm 89in x 102in	Bilateral Adhesive Split Sheet
9047	183cm x 152cm 72in x 60in	Neuro Split Sheet with Pouch
9048	20cm x 40cm (split) 7in x 15 in 228cm x 260cm 90in x 102in	Adhesive Split Sheet
9050	12cm x 18cm (aperture) 4.5in x 8in 228cm x 300cm 90in x 138in	Adhesive Aperture Drape

Catalog Number(s)	Dimensions	Name/Descriptor
9051	183cm x 315cm 72in x 124in	Thyroid Drape
9052	355cm x 293cm 140in x 115in	Hand Drape
9053	228cm x 300cm 89in x 118in	Extremity Drape
9054	195cm x 300cm 77in x 118in	Hand and Foot Drape
9055	300cm · 118in (Width Top) 228cm · 90in (Width Bottom) 353cm · 139in (Length)	Hip Drape with Pouches
9056	195cm x 300cm 77in x 118in	Bilateral Foot Drape
9057	292cm · 115in (Width Top) 228cm · 89in (Width Bottom) 305cm · 120in (Length)	Extremity Drape with Anesthesia Screen
9058	228cm x 300cm 90in x 118in	Bilateral Knee Drape
9062	254cm · 100in (Width Top) 183cm · 72in (Width Bottom) 285cm · 112in (Length)	Laparotomy Drape-Transverse
9063	254cm · 100in (Width Top) 183cm · 72in (Width Bottom) 285cm · 112in (Length)	Laparotomy Drape
9066	85cm x 85cm 33in x 33in	Under Buttock Drape with Cuff
9067	45cm x 37cm 17.75in x 14.5in	Drape Sheet
9069	90cm x 75cm 36in x 30in	Drape Sheet
9070	114cm x 87cm 45in x 34in	Turban Drape Sheet
9071	97cm x 97cm 38 in x 38in	Drape Sheet
9072	114cm x 150cm 44in x 59in	Drape Sheet
9074	150cm x 150cm 60in x 60in	Instrument Table Cover/Drape Sheet
9077	200cm x 250cm 78in x 59in	Drape Sheet
9077R	150cm x 200cm No inches stated	Instrument Table Cover Reinforced
9079	200cm x 228cm 78in x 90in	Drape Sheet

Catalog Number(s)	Dimensions	Name/Descriptor
9083	55cm x 55cm 19.75in x 19.75in	Adhesive Towel Drape
9084	75cm x 75cm 29in x 29in	Adhesive Towel Drape
9085	100cm x 85cm 39in x 33in	Adhesive Towel Drape
9085W	97cm x 115cm 38in x 45in	Adhesive Towel Drape
9086	100cm x 75cm 39in x 29in	Adhesive Towel Drape
9087	183cm x 183cm 72in x 72in	Adhesive Drape Sheet
9088	200cm x 250cm 78in x 59in	Adhesive Drape Sheet
9089	170cm x 170cm 67in x 67in	Adhesive Drape Sheet
9090	300cm x 228cm 118in x 90in	Adhesive Drape Sheet
9196	16cm x 95cm (Split) 6in x 37in 228cm x 260cm 90in x 102in	Shoulder Split Sheet with Pouch

The above catalog numbers are also available in non-sterile versions and are designated by NS following the catalog number.

*Note: 1190NS and 9033NS are only available in a non-sterile version.

Table 1 – Product Catalog Numbers, Dimensions and Name/Descriptor

Catalog Number(s)	Dimensions	Name/Descriptor
1031	27cm x 30cm 10.5in x 11.5in (Aperture) 228cm · 90in (Width Top) 182cm · 72in (Width Bottom) 285cm · 112in (Length)	Laparoscopic Drape/Supine Position
1032	27cm x 30cm 10.5in x 11.5in (Aperture 1) 12cm x 15.5cm 4.5in x 6cm (Aperture 2) 228cm · 90in (Width Top) 117cm · 46in (Length of Panel) 241cm · 95in (Length)	Laparoscopic Drape/Lithotomy Position
1034	34.5cm x 34.5cm (13.5in x 13.5in) Film with 10cm (4 in) Circle Aperture 152cm x 200cm 60in x 78in	Central Venous Catheter Drape
1078	9cm x 12cm 3.3in x 4.5in (Aperture) 196cm x 200cm 77in x 78in	Perineal Drape with Pouch
1079	9cm x 12cm 3.3in x 4.5in (Aperture) 195cm · 77in (Width Top) 117cm · 46in (Length of Panel) 179cm · 70in (Length)	Gynecologic Drape
1080	9cm x 12cm 3.3in x 4.5in (Aperture) 195cm · 77in (Width Top) 117cm · 46in (Length of Panel) 179cm · 70in (Length)	Gynecologic Drape
1081	20cm x 10cm (7.8in x 3.9in) Film with 6cm (2 in) Circle Aperture 152cm x 164cm (60in x 64in) 117cm · 46in (Length of Panel)	TUR/Urological Drape

Catalog Number(s)	Dimensions	Name/Descriptor
1082	23cm x 28cm 9in x 11in (Aperture) 235cm · 92 in (Width) 300cm · 118 in (Length)	Abdominal Vaginal Drape
1084	86cm x 63cm 34in x 24.5in (Pouch) 86cm x 45cm 34in x 17.5in	Under Buttocks Drape with Pouch
1089	57cm x 66cm 22in x 26in	Utility Sheet (2)
1090	6.4cm x 8.9cm 2.5in x 3.5in (Aperture) 182cm x 228cm 72in x 90in	Femoral Angiography Drape
1092	6cm · 2.25in (Circle Aperture) 57cm x 66cm 22in x 25in	Small Drape with Adhesive Aperture
1094	23cm x 28cm (9in x 11in) Film with 6cm (2.25in) Circle Aperture 226cm x 320cm 90in x 126in	Arthroscopy Sheet with Pouch
1135	28cm x 26cm (11in x 10in) Film with 15cm x 13cm (5.9in x 5in) Aperture 183cm x 279cm 72in x 110in	Peripherally Inserted Central Catheter Drape
*1190NS	10cm x 7.5cm 4in x 3in (Aperture) 91cm x 330cm 35in x 130in 228cm x 330cm 89in x 130in	Femoral Angiography Drape
1191	11cm x 14cm 4in x 5.5in (Aperture) 91cm x 228cm 35in x 89in 229cm x 330cm 90in x 130in	Femoral Angiography Drape
1192	8cm x 20cm 3in x 7.5in (Aperture) 152cm x 170cm 60in x 67in	Venous/Arterial Access Drape

Catalog Number(s)	Dimensions	Name/Descriptor
1193	7.5cm x 10cm 3in x 4in (Aperture) 154cm x 154cm 60in x 60in 290cm x 345cm 114in x 136in	Angiography Drape
1194	23cm x 28cm (9in x 11in) Film with 6cm (2.25in) Circle Aperture 292cm · 115in (Width Top) 228cm · 89in (Width Bottom) 304cm · 120in (Length)	Arthroscopy Sheet with Pouch
2065	41cm x 45cm (16in x 17in) Incise 12cm x 15.5cm (4.75in x 6in) Aperture 195cm · 77in 271cm · 106in 117cm · 46in (Length of Panel)	Abdominoperineal Incise Drape
7964	30cm x 30cm 12in x 12in (Incise) 254cm x 279cm 100in x 110in	Abdominoperineal Incise Drape- Lithotomy Position
7965	30cm x 30cm 12in x 12in (Incise) 254cm · 100in (Width Top) 195cm · 76in (Width Bottom) 308cm · 121in (Length)	Cesarean Section Incise Sheet with Pouch
7966	30cm x 30cm 12in x 12in (Incise) with 20cm x 24 cm (8in x 9.5in) Aperture 254cm · 100in (Width Top) 195cm · 76in (Width Bottom) 310cm · 122in (Length)	Cesarean Section Sheet with Aperture Pouch
9023	6cm x 8cm 2.3in x 3.1in (Aperture) 76cm x 170cm 29in x 67in	Perineal Aperture Drape
9026	6cm x 8cm 2.3in x 3.1in (Aperture) 55cm x 55cm 21in x 21in	Aperture Drape

Catalog Number(s)	Dimensions	Name/Descriptor
9027	11cm x 12.5cm 4in x 5in (Aperture) Part 1 50cm x 75cm 19in x 29in Part 2 50cm x 75cm 19in x 29in	Adjustable Aperture Drape
9027L	11cm x 12.5cm 4in x 5in (Aperture) Part 1 75cm x 100cm 29in x 39in Part 2 75cm x 100cm 29in x 39in	Adjustable Adhesive Aperture Drape
9028	6cm x 8cm 2.3in x 3.1in (Aperture) 75cm x 75cm 29in x 29in	Adhesive Aperture Drape
9029	15 cm x 6 cm 6in x 2in (Aperture) 75cm x 75cm 29in x 29in	Adhesive Aperture Drape
9030	6cm x 8cm 2in x 3in (Aperture) 152cm x 120cm 60in x 47in	Adhesive Aperture Drape
9031	8cm x 6cm 3in x 2in (Aperture) 150cm x 183cm 59in x 72in	Adhesive Aperture Drape
*9033NS	12cm x 11cm 4.5in x 4in (Aperture) 150cm x 183cm 59in x 72in	Triangular Aperture Drape
9040	75cm x 114cm (includes foldover) 29in x 44in	Leggings (2)
9040L (pair)	85cm x 130cm (includes foldover) 33in x 51in	Legging Long
9041	35cm x 60cm (includes foldover) 13.5in x 23.5in	Extremity Cover (S)
9042	35cm x 100cm (includes foldover) 13.5in x 39in	Extremity Cover (L)

Catalog Number(s)	Dimensions	Name/Descriptor
9043	7cm x 70cm 2.5in x 25in (Split) 152cm x 183cm 60in x 72in	Adhesive Split Sheet
9044	7cm x 70cm 2.5in x 25in (Split) 152cm x 250cm 60in x 98in	Adhesive Split Sheet
9045	20cm x 100cm 7in x 39 in (Split) 228cm x 260cm 89.5in x 102in	Adhesive Split Sheet
9045R	20cm x 100cm 7in x 39 in (Split) 228cm x 260cm 89.5in x 102in	Reinforced Adhesive Split Sheet
9046	15cm x 50 cm 6in x 19in (Split) 183cm x 200cm 72in x 78in	Bilateral Adhesive Split Sheet
9046L	44cm x 100cm 17in x 39in (Split) 228cm x 260cm 90in x 102in	Bilateral Adhesive Split Sheet
9047	16cm x 40cm 6in x 15in (Split) 183cm x 152cm 72in x 60in	Neuro Split Sheet with Pouch
9048	20cm x 40cm 7in x 15in (Split) 228cm x 260cm 90in x 102in	Adhesive Split Sheet
9050	12cm x 16 cm 4.5in x 6in (Aperture) 228cm x 300cm 90in x 118in	Adhesive Aperture Drape
9051	12cm x 12cm 4.5in x 4.5in (Aperture) 183cm x 315cm 72in x 124in	Thyroid Drape

Catalog Number(s)	Dimensions	Name/Descriptor
9052	15cm x 25cm (5.9in x 9.8in) Film with 3cm (1 in) Circle Aperture 355cm x 293cm 140in x 115in	Hand Drape
9053	11cm x 26cm (4.3in x 10in) Film with 6cm x 8cm (2in x 3in) Aperture 228cm x 300cm 89in x 118in	Extremity Drape
9054	15cm x 25 cm (5.9in x 9.8in) Film with 3cm (1 in) Circle Aperture 195cm x 300cm 77in x 118in	Hand and Foot Drape
9055	34cm x 39cm (13in x 15in) Film with 20cm x 17.5cm (8in x 7in) Aperture 300cm · 118in (Width Top) 57cm · 22in (Width Bottom) 353cm · 139in (Length) 246cm 96in (Length of Pouches) 228cm · 90in (Total Overall Width Bottom)	Hip Drape with Pouches
9056	25cm x 50cm (9.8in x 19.6 in) Film with 4cm (1.5in) Circle Aperture 195cm x 300cm 77in x 118in	Bilateral Foot Drape
9057	11cm x 26 cm (4.3in x 10in) Film with 6cm x 8cm (2in x 3in) Aperture 292cm · 115in (Width Top) 228cm · 89in (Width Bottom) 305cm · 120in (Length)	Extremity Drape with Anesthesia Screen
9058	11cm x 26 cm (4.3in x 10in) Film with 6cm x 8cm (2in x 3in) Aperture 228cm x 300cm 90in x 118in	Bilateral Knee Drape

Catalog Number(s)	Dimensions	Name/Descriptor
9062	30cm x 10cm 12in x 4in (Aperture) 254cm · 100in (Width Top) 183cm · 72in (Width Bottom) 285cm · 112in (Length)	Laparotomy Drape-Transverse
9063	10cm x 30cm 4in x 12in (Aperture) 254cm · 100in (Width Top) 183cm · 72in (Width Bottom) 285cm · 112in (Length)	Laparotomy Drape
9066	85cm x 85cm 33in x 33in Cuff is 25 cm of the 85 cm.	Under Buttock Drape with Cuff
9067	45cm x 37cm 17.75in x 14.5in	Drape Sheet
9069	90cm x 75cm 36in x 30in	Drape Sheet
9070	114cm x 87cm 45in x 34in	Turban Drape Sheet
9071	97cm x 97cm 38 in x 38in	Drape Sheet
9072	114cm x 150cm 44in x 59in	Drape Sheet
9074	150cm x 150cm 59in x 59in	Instrument Table Cover/Drape Sheet
9077	200cm x 150cm 78in x 59in	Drape Sheet
9079	200cm x 228cm 78in x 90in	Drape Sheet
9083	55cm x 55cm 19.75in x 19.75in	Adhesive Towel Drape
9084	75cm x 75cm 29in x 29in	Adhesive Towel Drape
9085	100cm x 85cm 39in x 33in	Adhesive Towel Drape
9085W	115cm x 97cm 45in x 38in	Adhesive Towel Drape
9086	100cm x 75cm 39in x 29in	Adhesive Towel Drape
9087	183cm x 183cm 72in x 72in	Adhesive Drape Sheet
9088	250 cm x 150 cm 98in x 59in	Adhesive Drape Sheet
9089	170cm x 170cm 67in x 67in	Adhesive Drape Sheet

Catalog Number(s)	Dimensions	Name/Descriptor
9090	300cm x 228cm 118in x 90in	Adhesive Drape Sheet
9196	16cm x 95cm 6in x 37in (Split) 228cm x 260cm 90in x 102in	Shoulder Split Sheet with Pouch

The above catalog numbers are also available in non-sterile versions and are designated by NS following the catalog number.

*Note: 1190NS and 9033NS are only available in a non-sterile version.

510(k) Summary K140330

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Owner's Name

3M Health Care
3M Center, Building 275-5W-06
St. Paul, MN 55144

Contact Person

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Date Summary Prepared

July 14, 2014

Trade/Proprietary Name

3M™ Steri-Drape™ Fabric Surgical Drapes

Common/Usual Name

Drapes, Surgical

Classification Name

Surgical drape and drape accessories

Product Code:

KKX per 21CFR 878.4370

Predicate Devices

3M Steri-Drape Surgical Fabric Drapes K031287

Intended Use

3M Steri-Drape Fabric Surgical Drapes are used to create a sterile field for surgical procedures. They are provided sterile and intended for external use only.

3M Steri-Drape non-sterile fabric drapes are provided to other manufacturers for further processing using ethylene oxide. 3M provides information on compatibility with ethylene oxide (EtO) processing.

Non-sterile surgical drapes are sold to repackager or relabeler establishments for EtO sterilization according to ISO 11135-1:2007. Sterile surgical drapes are sold directly to end users after EtO sterilization validation to ISO 11135-1:2007.

Description of Device

The 3M Steri-Drape Fabric Surgical Drapes are one-piece, dual layer, single use disposable drapes with an AAMI Level 4 Liquid Barrier. The drapes are made of a blue absorbent nonwoven fabric thermally bonded to a blue protective barrier film. The drapes are intended to be placed over the patient prior to surgery and are designed to provide an absorbent sterile barrier during surgical procedures and stop fluid strike-through to protect the surgical site and patient from microbial penetration.

Steri-Drape Fabric Surgical Drapes are either provided sterile to end-users or non-sterile to kit manufacturers for further processing including EtO sterilization according to ISO 11135-1:2007

The drapes are provided in multiple sizes and shapes to meet the requirements of various clinical procedures. In general, the surgeon delineates the proposed field of surgery and charges the nursing team with the responsibility of draping the patient using different types of drapes. All models utilize the same material technology.

The following tables list the catalog numbers of the drapes that are included within the scope of this submission. The drapes are separated into categories based on similarity of the design and features. The categories are as follows:

Category 1 – These drapes are comprised entirely of a non-woven/film construction and may or may not feature an aperture. The entire non-woven/film portion of the drape is considered an AAMI Level 4 Barrier, with the barrier continuing to the edge of the aperture. Any component material attached to or configured within the aperture is identical to that used in the corresponding, currently marketed, predicate drapes.

Category 2 –These drapes are comprised of a non-woven / film construction and also contain either a film area with aperture or incise area. The AAMI Level 4 Barrier non-woven/film portion of the drape continues to the edge of the film or incise area. The component materials of the film area with aperture or incise area are identical to those used in the corresponding, currently marketed, predicate drapes.

Category 3 - These drapes are comprised entirely of a non-woven/film construction and feature an aperture. Additionally, these drapes include an extra absorbent layer on top of the drape and side film segments. The entire non-woven/woven portion of the drape is considered an AAMI Level 4 Barrier with the barrier continuing to the edge of the aperture. The extra absorbent layer on top of the drape are illustrated with a crosshatch, and side film segments are identical to those used in the corresponding, currently marketed, predicate drapes and do not impact barrier performance of the non-woven/film portion.

Category 1

Catalog Number(s)	Approximate Dimensions	Name/Descriptor	AAMI Level 4 Barrier
1031 1031NS	27cm x 30cm 10.5in x 11.5in (Aperture) 228cm · 90in (Width Top) 182cm · 72in (Width Bottom) 285cm · 112in (Length)	Laparoscopic Drape/Supine Position	Entire drape except aperture
1032 1032NS	27cm x 30cm 10.5in x 11.5in (Aperture 1) 12cm x 15.5cm 4.5in x 6cm (Aperture 2) 228cm · 90in (Width Top) 117cm · 46in (Length of Panel) 241cm · 95in (Length)	Laparoscopic Drape/Lithotomy Position	Entire drape except aperture
1078 1078NS	9cm x 12cm 3.3in x 4.5in (Aperture) 196cm x 200cm 77in x 78in	Perineal Drape with Pouch	Entire drape except aperture
1079 1079NS	9cm x 12cm 3.3in x 4.5in (Aperture) 195cm · 77in (Width Top) 117cm · 46in (Length of Panel) 179cm · 70in (Length)	Gynecologic Drape	Entire drape except aperture
1080 1080NS	9cm x 12cm 3.3in x 4.5in (Aperture) 195cm · 77in (Width Top) 117cm · 46in (Length of Panel) 179cm · 70in (Length)	Gynecologic Drape with Pouch	Entire drape except aperture
1082 1082NS	23cm x 28cm 9in x 11in (Aperture) 235cm · 92 in (Width) 300cm · 118 in (Length)	Abdominal Vaginal Drape	Entire drape except aperture

Catalog Number(s)	Approximate Dimensions	Name/Descriptor	AAMI Level 4 Barrier
1084 1084NS	86cm x 63cm 34in x 24.5in (Pouch) 86cm x 45cm 34in x 17.5in	Under Buttocks Drape with Pouch	Entire drape
1089 1089NS	57cm x 66cm 22in x 26in	Utility Sheet	Entire drape
1090 1090NS	6.4cm x 8.9cm 2.5in x 3.5in (Aperture) 182cm x 228cm 72in x 90in	Femoral Angiography Drape	Entire drape except aperture
1092 1092NS	6cm · 2.25in (Circle Aperture) 57cm x 66cm 22in x 25in	Small Drape with Adhesive Aperture	Entire drape except aperture
1192 1192NS	8cm x 20cm 3in x 7.5in (Aperture) 152cm x 170cm 60in x 67in	Venous/Arterial Access Drape	Entire drape except aperture
9023 9023NS	6cm x 8cm 2.3in x 3.1in (Aperture) 76cm x 170cm 29in x 67in	Perineal Aperture Drape	Entire drape except aperture
9026 9026NS	6cm x 8cm 2.3in x 3.1in (Aperture) 55cm x 55cm 21in x 21in	Aperture Drape	Entire drape except aperture
9027 9027NS	11cm x 12.5cm 4in x 5in (Aperture) Part 1 50cm x 75cm 19in x 29in Part 2 50cm x 75cm 19in x 29in	Adjustable Aperture Drape	Entire drape except aperture
9027L 9027LNS	11cm x 12.5cm 4in x 5in (Aperture) Part 1 75cm x 100cm 29in x 39in Part 2 75cm x 100cm 29in x 39in	Adjustable Adhesive Aperture Drape	Entire drape except aperture

Catalog Number(s)	Approximate Dimensions	Name/Descriptor	AAMI Level 4 Barrier
9028 9028NS	6cm x 8cm 2.3in x 3.1in (Aperture) 75cm x 75cm 29in x 29in	Adhesive Aperture Drape	Entire drape except aperture
9029 9029NS	15 cm x 6 cm 6in x 2in (Aperture) 75cm x 75cm 29in x 29in	Adhesive Aperture Drape	Entire drape except aperture
9030 9030NS	6cm x 8cm 2in x 3in (Aperture) 152cm x 120cm 60in x 47in	Adhesive Aperture Drape	Entire drape except aperture
9031 9031NS	8cm x 6cm 3in x 2in (Aperture) 150cm x 183cm 59in x 72in	Adhesive Aperture Drape	Entire drape except aperture
*9033NS	12cm x 11cm 4.5in x 4in (Aperture) 150cm x 183cm 59in x 72in	Triangular Aperture Drape	Entire drape except aperture
9040 9040NS	75cm x 114cm 29in x 44in	Extremity Drape (Leggings)	Entire drape
9040L 9040LNS	85cm x 130cm 33in x 51in	Extremity Drape (Leggings Long)	Entire drape
9041 9041NS	35cm x 60cm 13.5in x 23.5in	Extremity Cover (S)	Entire drape
9042 9042NS	35cm x 100cm 13.5in x 39in	Extremity Cover (L)	Entire drape
9043 9043NS	7cm x 70cm 2.5in x 25in (Split) 152cm x 183cm 60in x 72in	Adhesive Split Sheet	Entire drape except aperture
9044 9044NS	7cm x 70cm 2.5in x 25in (Split) 152cm x 250cm 60in x 98in	Adhesive Split Sheet	Entire drape except aperture

Catalog Number(s)	Approximate Dimensions	Name/Descriptor	AAMI Level 4 Barrier
9045 9045NS	20cm x 100cm 7in x 39 in (Split) 228cm x 260cm 89.5in x 102in	Adhesive Split Sheet	Entire drape except aperture
9046 9046NS	15cm x 50cm 6in x 19in (Split) 183cm x 200cm 72in x 78in	Bilateral Adhesive Split Sheet	Entire drape except aperture
9046L 9046LNS	44cm x 100cm 17in x 39in (Split) 228cm x 260cm 90in x 102in	Bilateral Adhesive Split Sheet	Entire drape except aperture
9047 9047NS	16cm x 40cm 6in x 15in (Split) 183cm x 152cm 72in x 60in	Neuro Split Sheet with Pouch	Entire drape except aperture
9048 9048NS	20cm x 40cm 7in x 15in (Split) 228cm x 260cm 90in x 102in	Adhesive Split Sheet	Entire drape except aperture
9050 9050NS	12cm x 16 cm 4.5in x 6in (Aperture) 228cm x 300cm 90in x 118in	Adhesive Aperture Drape	Entire drape except aperture
9051 9051NS	12cm x 12cm 4.5in x 4.5in (Aperture) 183cm x 315cm 72in x 124in	Thyroid Drape	Entire drape except aperture
9062 9062NS	30cm x 10cm 12in x 4in (Aperture) 254cm · 100in (Width Top) 183cm · 72in (Width Bottom) 285cm · 112in (Length)	Laparotomy Drape-Transverse	Entire drape except aperture
9063 9063NS	10cm x 30cm 4in x 12in (Aperture) 254cm · 100in (Width Top) 183cm · 72in (Width Bottom) 285cm · 112in (Length)	Laparotomy Drape	Entire drape except aperture

Catalog Number(s)	Approximate Dimensions	Name/Descriptor	AAMI Level 4 Barrier
9066 9066NS	85cm x 85cm 33in x 33in	Under Buttock Drape with Cuff	Entire drape
9067 9067NS	45cm x 37cm 17.75in x 14.5in	Drape Sheet	Entire drape
9069 9069NS	90cm x 75cm 36in x 30in	Drape Sheet	Entire drape
9070 9070NS	114cm x 87cm 45in x 34in	Turban Drape Sheet	Entire drape
9071 9071NS	97cm x 97cm 38 in x 38in	Drape Sheet	Entire drape
9072 9072NS	114cm x 150cm 44in x 59in	Drape Sheet	Entire drape
9074 9074NS	150cm x 150cm 59in x 59in	Drape Sheet	Entire drape
9077 9077NS	200cm x 150cm 78in x 59in	Drape Sheet	Entire drape
9079 9079NS	200cm x 228cm 78in x 90in	Drape Sheet	Entire drape
9083 9083NS	55cm x 55cm 19.75in x 19.75in	Adhesive Towel Drape	Entire drape
9084 9084NS	75cm x 75cm 29in x 29in	Adhesive Towel Drape	Entire drape
9085 9085NS	100cm x 85cm 39in x 33in	Adhesive Towel Drape	Entire drape
9085W 9085WNS	115cm x 97cm 45in x 38in	Adhesive Towel Drape	Entire drape

Catalog Number(s)	Approximate Dimensions	Name/Descriptor	AAMI Level 4 Barrier
9086 9086NS	100cm x75cm 39in x 29in	Adhesive Towel Drape	Entire drape
9087 9087NS	183cm x 183cm 72in x 72in	Adhesive Drape Sheet	Entire drape
9088 9088NS	250cm x 150cm 98in x 59in	Adhesive Drape Sheet	Entire drape
9089 9089NS	170cm x 170cm 67in x 67in	Adhesive Drape Sheet	Entire drape
9090 9090NS	300cm x 228cm 118in x 90in	Adhesive Drape Sheet	Entire drape
9196 9196NS	16cm x 95cm 6in x 37in (Split) 228cm x 260cm 90in x 102in	Shoulder Split Sheet with Pouch	Entire drape except aperture

Category 2

1034 1034NS	34.5cm x 34.5cm (13.5in x 13.5in) Film with 10cm (4 in) Circle Aperture 152cm x 200cm 60in x 78in	Central Venous Catheter Drape	Entire drape except film aperture
1081 1081NS	20cm x 10cm (7.8in x 3.9in) Film with 6cm (2 in) Circle Aperture 152cm x164cm 60in x 64in Upper 117cm (46in) Lower	TUR/Urological Drape	Entire drape except film aperture
1094 1094NS	23cm x 28cm (9in x 11in) Film with 6cm (2.25in) Circle Aperture 226cm x 320cm 90in x 126in	Arthroscopy Sheet with Pouch	Entire drape except film aperture

1135 1135NS	28cm x 26cm (11in x 10in) Film with 15cm x 13cm (5.9in x 5in) Aperture 183cm x 279cm 72in x 110in	Peripherally Inserted Central Catheter Drape	Entire drape except film aperture
1194 1194NS	23cm x 28cm (9in x 11in) Film with 6cm (2.25in) Circle Aperture 292cm · 115in (Width Top) 228cm · 89in (Width Bottom) 304cm · 120in (Length)	Arthroscopy Sheet with Pouch	Entire drape except film aperture
2065 2065NS	41cm x 45cm (16in x 17in) Incise 12cm x 15.5cm (4.75in x 6in) Aperture 195cm · 77in 271cm · 106in	Abdominoperineal Incise Drape	Entire drape except incise and aperture
7964 7964NS	30cm x 30cm 12in x 12in (Incise) 254cm x 279cm 100in x 110in	Abdominoperineal Incise Drape-Lithotomy Position	Entire drape except incise
7965 7965NS	30cm x 30cm 12in x 12in (Incise) 254cm · 100in (Width Top) 195cm · 76in (Width Bottom) 308cm · 121in (Length)	Cesarean Section Incise Sheet with Pouch	Entire drape except incise
7966 7966NS	30cm x 30cm 12in x 12in (Incise) with 20cm x 24 cm (8in x 9.5in) Aperture 254cm · 100in (Width Top) 195cm 76in (Width Bottom) 310cm · 122in (Length)	Cesarean Section Sheet with Aperture Pouch	Entire drape except incise with aperture

9052 9052NS	15cm x 25cm (5.9in x 9.8in) Film with 3cm (1 in) Circle Aperture 355cm x 293cm 140in x 115in	Hand Drape	Entire drape except film aperture
9053 9053NS	11cm x 26cm (4.3in x 10in) Film with 6cm x 8cm (2in x 3in) Aperture 228cm x 300cm 89in x 118in	Extremity Drape	Entire drape except film aperture
9054 9054NS	15cm x 25 cm (5.9in x 9.8in) Film with 3cm (1 in) Circle Aperture 195cm x 300cm 77in x 118in	Hand and Foot Drape	Entire drape except film aperture
9055 9055NS	34cm x 39cm (13in x 15in) Film with 20cm x 17.5cm (8in x 7in) Aperture 300cm · 118in (Width Top) 228cm · 90in (Width Bottom) 353cm · 139in (Length) 246cm · 96in (Length of Pouches) 228cm · 90in (Total Overall Width Bottom)	Hip Drape with Pouches	Entire drape except film aperture
9056 9056NS	25cm x 50cm (9.8in x 19.6 in) Film with 4cm (1.5in) Circle Aperture 195cm x 300cm 77in x 118in	Bilateral Foot Drape	Entire drape except film aperture
9057 9057NS	11cm x 26 cm (4.3in x 10in) Film with 6cm x 8cm (2in x 3in) Aperture 292cm · 115in (Width Top) 228cm · 89in (Width Bottom) 305cm · 120in (Length)	Extremity Drape with Anesthesia Screen	Entire drape except film aperture

9058 9058NS	11cm x 26 cm (4.3in x 10in) Film with 6cm x 8cm (2in x 3in) Aperture 228cm x 300cm 90in x 118in	Bilateral Knee Drape	Entire drape except film aperture
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Category 3

*1190NS	10cm x 7.5cm 4in x 3in (Aperture) 91cm x 330cm 35in x 130in 228cm x 330cm 89in x 130in (Film)	Femoral Angiography Drape	Fabric drape except aperture
1191 1191NS	11cm x 14cm 4in x 5.5in (Aperture) 91cm x 228cm 35in x 89in 229 x 330cm 90in x 130in (Film)	Femoral Angiography Drape	Fabric drape except aperture
1193 1193NS	7.5cm x 10cm 3in x 4in (Aperture) 154cm x 154cm 60in x 60in 290cm x 345cm 114 x 136in (Film)	Angiography Drape	Fabric drape except aperture
9045R 9045RNS	20cm x 100cm 7in x 39 in (Split) 228cm x 260cm 89.5in x 102in	Reinforced Adhesive Split Sheet	Fabric drape except aperture

The catalog numbers contained in the Category 1, 2 and 3 tables are also available in non-sterile versions and are designated by NS following the catalog number.

*The 1190NS and 9033NS are only available in a non-sterile version.

Technological Characteristics

The scientific characteristics, how the device functions, and the barrier properties of the device described in this submission compared to the predicate have not fundamentally changed. The device is designed to act as a protective barrier to stop fluid strike-through to inhibit the transfer of blood, body fluids and other potentially infectious materials. The primary change is to the non-woven material, which as testing has demonstrated, is substantially equivalent in performance to the predicate.

Summary of Non-Clinical Performance Testing

3M Steri-Drape Fabric Surgical Drapes have been evaluated and tested in accordance with the applicable requirements recommended in the FDA' Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes, Infection Control Devices Branch Division of General and Restorative Devices, August 1993 as well as FDA recognized consensus standards, including non-clinical performance testing to the following standards:

- ANSI/AAMI PB70: 2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities
- ASTM F1670-08 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood
- ISO 9073-3:1989 – Textiles – Test methods for nonwovens – Part 3: Determination of tensile strength and elongation
- ISO 13938-1:1999 – Textiles – Bursting properties of fabrics – Part 1: Hydraulic method for determination of bursting strength and bursting distention
- ISO 9073-10:2003 – Textiles – Test methods for nonwovens – Part 10: Lint and other particles generation in the dry state
- 16 CFR Part 1610: Standard for the Flammability of Clothing Textiles
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.

In accordance with the above applicable standards and test methods, non-clinical performance testing was conducted using the sterilized, final finished device and consisted of the following tests in order to demonstrate substantial equivalence:

- Tensile strength
- Burst strength
- Resistance to liquid penetration
- Linting and particulate
- Flammability
- Biocompatibility (cytotoxicity, irritation and sensitization)

The non-clinical performance testing summary is as follows:

Non-Clinical Performance Test	Test Objective	Test Method	Data Summary		Substantial Equivalence Comparison
			Test Article: 3M™ Steri-Drape™ Fabric Surgical Drape	Predicate: 3M™ Steri-Drape™ Fabric Surgical K031287	
Tensile Strength	Drape must have adequate strength for surgical procedures.	Test per ISO 9073-3	Machine Direction (MD) = 106 N Cross Direction (CD) = 58	Machine Direction (MD) = 108 N Cross Direction (CD) = 70.7 N	Substantially Equivalent
Burst Strength	Drape must have adequate strength for surgical procedures.	Test per ISO 13938-1	Dry = 231 kPa Wet = 193 kPa	Dry = 225 kPa Wet = 199 kPa	Substantially Equivalent
Resistance to Liquid Penetration	Drape must be resistant to strikethrough from blood and bodily fluids and potential infectious agents.	AMMI PB 70 tested to ASTM F1670	AAMI Level 4 – Pass with an AQL of 4% and RQL of 20%	AAMI Level 4 - Pass with an AQL of 4% and RQL of 20%	Substantially Equivalent

Linting	Drape must have low levels of foreign matter.	Tested to ISO 9073-10	Pass with a Log ₁₀ (lint count) of ≤ 4,0	Pass with a Log ₁₀ (lint count) of ≤ 4,0	Substantially Equivalent
Particulate	Drape must have low levels of foreign matter.	Tested to ISO 9073-10	Pass with an Index Particulate Matter (IPM) of ≤ 3, 5	Pass with an Index Particulate Matter (IPM) of ≤ 3, 5	Substantially Equivalent
Flammability	Drape must have low potential for flammability and flame spread.	Tested to 16 CFR Part 1610	Class I Normal	Class I Normal	Substantially Equivalent
Cytotoxicity	Drape must have low potential for cytotoxic reaction.	Tested to ISO 10993-5	Non-Cytotoxic	Non-Cytotoxic	Substantially Equivalent
Irritation	Drape must have low potential as an irritant.	Tested to ISO 10993-10	Non-Irritating	Non-Irritating	Substantially Equivalent
Sensitization	Drape must have low potential as a sensitizer.	Tested to ISO 10993-10	Non-Sensitizing	Non-Sensitizing	Substantially Equivalent

All of the non-clinical performance testing results met the stated acceptance criteria. The test results support the determination of substantial equivalence to the predicate device under K031287 and have met or exceeded the predicate device's performance and establish that the changes do not impact safety or effectiveness or raise new questions about safety and effectiveness.

Substantial Equivalence

The 3M Steri-Drape Fabric Surgical Drapes have substantially equivalent product and performance characteristics and intended use as the 3M devices currently on the market under K031287. Further, data shows a substantial equivalence in the performance of these devices and the fundamental scientific technology has not been altered. Therefore, because of the similarities to the predicate device, the minor differences do not present any new safety or effectiveness issues and the device is substantially equivalent to the predicate.

Substantial Equivalence Comparison

	3M Steri-Drape Fabric Surgical Drapes	3M Steri-Drape Surgical Fabric Drapes K031287 (Predicate)
Indications for Use	<p>3M Steri-Drape Fabric Surgical Drapes are used to create a sterile field for surgical procedures. They are provided sterile and intended for external use only.</p> <p>3M Steri-Drape non-sterile fabric drapes are provided to other manufacturers for further processing using ethylene oxide. 3M provides information on compatibility with ethylene oxide processing.</p> <p>Non-sterile surgical drapes are sold to repackager or relabeler establishments for EtO sterilization according to ISO 11135-1:2007. Sterile surgical drapes are sold directly to end users after EtO sterilization validation to ISO 11135-1:2007.</p>	<p>3M Steri-Drape Surgical Fabric Drapes are used to create a sterile field for surgical procedures. They are provided sterile using ethylene oxide or gamma radiation and intended for external use only.</p> <p>3M Steri-Drape non-sterile fabric drapes are provided to other manufacturers for further processing using ethylene oxide. 3M provides information on compatibility with ethylene oxide processing.</p>
Principles of Operation	<p>The drapes cover the patient and are made of an absorbent nonwoven fabric backed with a protective barrier film that stops fluid strike-through and are designed to protect the surgical site and patient from microbial penetration</p>	<p>The drapes cover the patient and are made of an absorbent nonwoven fabric backed with a protective barrier film that stops fluid strike-through and are designed to protect the surgical site and patient from microbial penetration</p>
Product Features	<p>Low linting, strong, conformable and easy to handle</p>	<p>Low linting, strong, conformable and easy to handle</p>

Nonwoven Layer	Poly lactide resin (PLA) Polypropylene resin (PP) Blue pigment blend in polymer matrix Proprietary surfactant blend	Polypropylene resin (PP) Titanium Dioxide Blue pigment blend in polymer matrix Proprietary surfactant
Barrier Film Layer	Ethylene-Methyl Acrylate (EMA) copolymers Hydrocarbon Resin Low Density Polyethylene resin (LDPE) Linear Low Density Polyethylene resin (LLDPE) Blue pigment blend in polymer matrix	Metallocene Ethylene Octene Copolymer Antiblock in polymer matrix Low Density Polyethylene resin (LDPE) Linear Low Density Polyethylene resin (LLDPE) Blue pigment blend in polymer matrix
Grams/M²	66 gsm	62 gsm
Packaging	Tyvek/Film	Tyvek/Film
Usage	Single Use	Single Use
Components	One-piece	One-piece
Configurations/Dimensions	Varies sizes and shapes to accommodate clinician needs	Various sizes and shapes to accommodate clinician needs
Method of Sterilization	Ethylene Oxide or Non-Sterile	Ethylene Oxide, Gamma Irradiation or Non-Sterile
Sterility Assurance Level	10 ⁻⁶	10 ⁻⁶
Shelf Life	3 Years	3 Years
Biocompatibility	Non-Cytotoxic Non-Sensitizing Non-Irritating	Non-Cytotoxic Non-Sensitizing Non-Irritating
AMMI Standard PB70 Barrier Level	Level 4	Level 4
Tensile Strength	MD = 106 N CD = 58.5 N	MD = 108 N CD = 70.7 N
Burst Strength	Dry = 231 kPa Wet = 193 kPa	Dry = 225 kPa Wet = 199 kPa
Flammability Rating	Class I Normal	Class I Normal
Linting	Pass with a Log ₁₀ (lint count) of ≤ 4,0	Pass with a Log ₁₀ (lint count) of ≤ 4,0

Particulate	Pass with an Index Particulate Matter (IPM) of $\leq 3, 5$	Pass with an Index Particulate Matter (IPM) of $\leq 3, 5$
Labeling	Brand name or common name listed Catalog number listed Drape dimensions and illustration on label AMMI Barrier Level Listed Single use statement Lot number listed Expiration date listed Not made with natural rubber latex statement Labeled as Ethylene Oxide or Not Sterile Sterile unless package is damaged or open statement Class I Normal flammability statement	Brand name or common name listed Catalog number listed Drape dimensions and illustration on label No AMMI Barrier Level Listed Do not reuse statement Lot number listed Expiration date listed Latex free statement Labeled as Ethylene Oxide, Gamma Sterile or Not Sterile Sterile unless package is damaged or open statement No flammability statement

Conclusion

Based on the results of the non-clinical performance and biocompatibility testing, the 3M Steri-Drape Fabric Surgical Drapes are as safe, as effective and are demonstrated to be substantially equivalent to the predicate device. The 3M Steri-Drape Fabric Surgical Drape is substantially equivalent to the predicate 3M Steri-Drape Surgical Fabric Drape K031287 in terms of intended use, physical performance testing, material composition, sterilization, biocompatibility, labeling and safety and effectiveness.