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K964364

510(k) Summary of Safety and Effectiveness

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Product:

Classification Name:	Surgical Apparel (21 CFR 878.4040)
Generic Name:	Apron
Trade/Proprietary Name:	Disposable Apron

Substantially Equivalent Product:

Sloan Medical, Disposable Surgical Jumpsuit
Associated Bag, Apron

Description:

The Disposable Apron is manufactured from 6 gauge Poly Vinyl and is available in a "one size fits most" size. The apron is secured by being slipped over the head and tied in back

Intended Use:

The Disposable Apron will be used in indications which are the same for that of other aprons. Specifically, the Disposable Apron is intended to be used the hospital environment to protect the healthcare worker from the transfer of micro-organisms, blood, body fluids and particulate material between the worker and the patient

The Disposable Apron is a disposable product intended for single use only.

Summary of the non-clinical tests from which substantial equivalence:

The Disposable Apron has the same intended use as Sloan Medical's Disposable Surgical Jumpsuit and Associated Bag's Apron. The designs are similar in that they both are secured around the neck and tied behind the back. The also cover the front of the body. The following table summarizes the non-clinical tests from which the substantial equivalence is based.

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	Sloan Medical Jumpsuit	Associated Bag Apron	Instrument Makar Apron
Intended Use	Protect user from fluids in hospital environment	Protect user from fluids in hospital environment	Protect user from fluids in hospital environment
Design	Ties around the neck and behind the back	Ties around the neck and behind the back	Ties around the neck and behind the back
Materials	2 mil Polyethylene	1 1/4 mil Polyethylene	6 Gauge Embossed Poly-Vinyl
Physical Safety	NA	NA	NA
Target Population	Hospital Personnel	Hospital Personnel	Hospital Personnel
Biocompatibility	Jumpsuit is worn over clothing, therefore will not be in contact with user's skin	Apron is worn over clothing, therefore will not be in contact with user's skin	Apron is worn over clothing, therefore will not be in contact with user's skin
Anatomical Sites	Cover front of body and feet	Cover front of body and feet	Cover front of body and feet
Additional Notes	Sold non-sterile	Sold non-sterile	Sold non-sterile

Summary of the Viral Penetration Test: ASTM Method F1671-95

The material from which the Apron is made, 6 gauge embossed Poly-Vinyl, is the same as Instrument Makar's Fluid Barrier Boots(K955835) are made.

Summary:

The oX174 bacteriophage challenge suspension will be maintained at a concentration of at least 1.0 X 108 PFU/mL (plaque forming units/mL).

Test samples were prepared by randomly cutting approximately 75mm x 75mm test swatches from the test material. Test samples were challenged with approximately 60 mL of a oX174 bacteriophage suspension for 5 minutes at atmospheric pressure, 1 minute at 2.0 PSIG (13.8 kpa), and 54 minutes at atmospheric pressure or until liquid penetration was observed. At the conclusion of the test, the observed side of the test sample was rinsed with a sterile assay medium and then assayed for the presence of the oX174 bacteriophage. The surface tension of the challenge suspension and the assay medium was adjusted to approximately 40-44 dynes/cm using surfactant-type Tween® 80 at a final concentration of approximately 0.01% by volume.

These samples were also tested for compatibility of materials and test organisms. This testing was done by placing a 10 uL aliquot of a oX174 suspension containing a total of 900-1200 PFU near the center of the test sample after it had been clamped into the penetration test cell. After 60 minutes, the surface was rinsed with a sterile assay medium and then assayed for the presence of the oX174 bacteriophage

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Results:

The compatibility ratio for the Fluid Barrier Boot was 1.3. The challenge level was maintained at ~1.3 x 108 PFU/ml

Thirty two samples of the Fluid Barrier Boot were tested according to the procedure described in this report. All thirty two passed showing no oX174 on the assay plates.