

NOV 22 1996

K955749

510 (K) Summary

11-22-96

Trade Name - Tex-Care Sterile Stockinette

Common Name - Sterile Stockinette

Classification Name - Drape, Surgical

Predicate Device : Burlington® Sterile Stockinette also known as Balfour Sterile Stockinette 510 (K) K82270

Description : Sterile stockinette includes single and double ply rolls, bias cut rolls and impervious stockinette in various widths and lengths.

Intended Use : Sterile stockinette is used primarily as an surgical extremity drape to establish a sterile field. Bias cut sterile stockinette is used as a dressing retainer where swelling is expected.

Technical Characteristics : Tex-Care Sterile Stockinette has the same technological characteristics as the predicate device with regard to design, materials, and method of manufacture.

The following tests were run on Tex-Care Sterile Stockinettes to indicate that they would function in a safe and effective manner.

ASTM ES 21 - Synthetic Blood Penetration Test was run on 32 samples of impervious stockinettes to substantiate the claim of being impervious. All samples passed.

ASTM ES 22 - Viral Penetration Test was run on 32 samples of impervious stockinettes to substantiate the claim of being impervious. All samples passed.

Biocompatibility testing :

USP Intracutaneous Test - This test was to determine if any chemicals that may leach or be extracted from the impervious stockinettes were capable of causing local irritation in the dermal tissues of the rabbit. No apparent irritation was observed in association with the test article extracts.

**Re: Tex-Care Sterile Stockinette 510 (k) Summary Biocompatibility Testing
Continued:**

USP Systemic Injection Test was run to screen the extracts of the impervious stockinette for potential toxic effects as a result of a single dose injection. None of the test animals showed any clinical signs consistent with toxicity at any time during the observation period.

Guinea Pig Maximization Test (Sensitization) (Magnusson-Kligman) was run to evaluate the allergic potential or sensitizing capacity of the impervious stockinettes. The impervious stockinette showed a 0% sensitization incidence.

ASTM D 5034-90 Standard Test Method for Breaking Force of Textile Fabric and ASTM D 3787-89 Bursting Strength of Knitted Goods (CRT) Ball Burst Test were performed on the stockinettes to indicate that the construction had adequate strength to perform as intended. Both burst strength and breaking force were shown to be adequate.

CS-191-53 Part 1610 Flammability of Clothing Textiles tests indicated that requirements of Classification 1 - Normal Flammability were met by both cotton and impervious stockinettes.

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