

**510(k) Premarket Notification
Surgical Fabrics
August 12, 1996**

K963226
**Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537**

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SECTION VII

Summary of Safety and Effectiveness

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Sponsor: Boston Scientific Corporation
One Scientific Place
Natick, MA 01760-1537

Contact Person: Carol J. Holloway
Regulatory Affairs Specialist

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Predicate Devices: Trelex Natural® Mesh
Supple Peri-Guard®
Gore-Tex® Soft Tissue Patch
Marlex® Mesh
Mersilene® Mesh

Description of Device: The Surgical Fabrics are woven or knitted from polymer fibers, and precut into patches for soft tissue reinforcement in surgical repair procedures.

Intended Uses: The proposed Surgical Fabrics are implants which are intended to reinforce soft tissue where weakness exists for the urological, gynecological and gastroenterological anatomy inclusive but not limited to the following procedures: pubourethral support, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor, bladder support, and sacro-colposuspension.

Substantial Equivalence: The proposed devices are *Substantially Equivalent* to the predicate currently marketed devices indicated for use for reinforcement of soft tissue areas where weakness exists.

Product Testing: The proposed devices have been tested and compared to the predicate devices. The results indicate that the proposed devices are *Substantially Equivalent* to the predicate devices in terms of performance characteristics tested.