510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

K960342

SEP 10 1996

Sponsor: Meadox Medicals, Inc.
A Division of Boston Scientific Corporation
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Device Name: HEMASHIELD FINESSE™ Ultra-Thin, Knitted Cardiovascular Patch

Predicate Devices: HEMASHIELD® Cardiovascular Fabrics (K955349)
Gore-Tex® Peripheral Vascular Patch (K821717)
Gore-Tex® Cardiovascular Patch (K811841)

Description of Device: The HEMASHIELD FINESSE™ Ultra-Thin, Knitted Cardiovascular Patch is a knitted polyester fabric, impregnated with bovine collagen and contains glycerol as a softening agent.

Intended Uses: The HEMASHIELD FINESSE™ Ultra-Thin, Knitted Cardiovascular Patch is indicated for cardiac and vascular patch grafting. The fabric is also recommended for use in patients requiring systemic heparinization prior to, or during, surgery.

Substantial Equivalence: The HEMASHIELD FINESSE™ Ultra-Thin, Knitted Cardiovascular Patch is identical to the HEMASHIELD® Knitted Double Velour Cardiovascular Fabric in materials, manufacturing processes, packaging and sterilization. The only difference is that the HEMASHIELD FINESSE™ Patch is thinner than the HEMASHIELD® Knitted Fabric. Testing has been performed that shows that the HEMASHIELD FINESSE™ Patch is substantially equivalent to the predicate devices.

Product Testing: The following tests have been performed on the HEMASHIELD FINESSE™ Ultra-Thin, Knitted Cardiovascular Patch:

Burst Strength -	equivalent to marketed product
Wall Thickness -	equivalent to marketed product
Suture Retention Strength -	equivalent to marketed product
Tensile Strength -	equivalent to marketed product
Water Permeability -	equivalent to marketed product
Suture Hole Elongation -	equivalent to marketed product

Biocompatibility Testing: The HEMASHIELD FINESSE™ Ultra-Thin, Knitted Cardiovascular Patch is identical in materials, processing, packaging and sterilization as the predicate HEMASHIELD® Cardiovascular Fabrics. As such, it is reasonable to assume that the device is also identical in biocompatibility to the predicate, which has been shown through testing performed in accordance with ISO 9000 Standards to be safe for their intended use.