

PREMARKET NOTIFICATION
 Meadox Medicals, Inc.
 ePTFE Vascular Grafts 3 - 5mm
 Friday, February 23, 1996

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 K960766

SUMMARY OF SAFETY & EFFECTIVENESS

GENERAL INFO: Sponsor - Meadox Medicals, Inc.
 Contact Person - Stephen B Anderson
 Submission Date - February 23, 1996

DEVICE INFO: Generic Name - Expanded Reinforced PTFE Vascular Graft
 Trade Name - Meadox Medicals, Inc., Expanded PTFE Vascular Graft
 Meadox Medicals, Inc., Expanded PTFE Vascular Graft w/External Support
 Classification Name - Vascular Graft Prosthesis (less than 6 mm)

PREDICATE DEVICES:

K-Number	Proprietary Name	Company
Preamendment	GORE-TEX® Vascular Graft	W.L. Gore & Associates
Preamendment	IMPRA® Vascular Graft	IMPRA, Inc.
K79 1810	IMPRA® Vascular Graft	IMPRA, Inc.
K81 1510	GORE-TEX® FEP Ringed Vascular Graft	W.L. Gore & Associates
K82 1716	Bard® PTFE Vascular Prosthesis	C.R. Bard, Incorporated
K83 0806	GORE-TEX® Vascular Graft	W.L. Gore & Associates
K84 2144	GORE-TEX® Stretch Vascular Graft	W.L. Gore & Associates
K88 0167	GORE-TEX® Removable FEP Ring Graft	W.L. Gore & Associates
K93 3590	Baxter Reinforced Expanded PTFE Graft	Baxter Healthcare, Corp.

DEVICE DESCRIPTION: The ePTFE_{MEADOX} Vascular Graft is comprised of an expanded polytetrafluoroethylene (ePTFE) core tube reinforced by a multi-filament PTFE yarn helically wound around the exterior of the tube. Externally supported grafts have a continuous PTFE spiral support coil wound around a portion of the graft.

BIOCOMPATIBILITY: Biocompatibility testing on the ePTFE_{MEADOX} Vascular Graft was performed on single-cycle steam sterilized grafts in accordance with the ISO-10993 standard for biological evaluation of medical devices. Carcinogenicity testing was not performed on ePTFE_{MEADOX} grafts due to the established nontoxic properties of the graft materials. These tests indicate that the ePTFE_{MEADOX} Vascular Graft is safe for its intended use.

INDICATIONS: The ePTFE_{MEADOX} Vascular Grafts are designed to repair or replace peripheral arteries and to provide vascular access. Mid-Flex grafts are specifically indicated for vascular access, as are Stepped grafts which are designed to reduce the risk of steal syndrome. Externally Supported Grafts are used where kinking and compression resistance are desired.

DESIGN MATERIALS: Design materials of the ePTFE_{MEADOX} Vascular Graft are substantially equivalent to the predicate devices identified above.

MANUFACTURING: The ePTFE_{MEADOX} Vascular Graft is produced by heating, stretching and winding an extruded polytetrafluoroethylene tube.

SPECIFICATIONS: Performance specifications of the ePTFE_{MEADOX} Vascular Graft are substantially equivalent to the range of performance specifications found in the previously identified predicate devices.

CONCLUSION: The Meadox Medicals, Inc., Vascular Graft has a level of safety and effectiveness comparable to currently marketed ePTFE Vascular Grafts.