

K955460

SUMMARY OF SAFETY & EFFECTIVENESS

GENERAL INFO: Sponsor - Meadox Medicals, Inc
Contact Person - Stephen B Anderson
Submission Date - November 22, 1995

MAY 30 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 (6 mm and greater)

PREDICATE DEVICES:

K Number	Proprietary Name	Company
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.

Cytotoxicity -	Passed
Sensitization -	Passed
Irritation or	
Intracutaneous Reactivity -	Passed
Systemic Toxicity (acute) -	Passed
Sub-chronic Toxicity (sub-acute) -	Passed
Genotoxicity/Mutagenicity -	Passed
Implantation -	Passed
Hemocompatibility (hemolysis) -	Passed
Chronic Toxicity -	Passed

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- INDICATIONS:** The MEADOX® ePTFE 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.
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|---|---------------------------------|
| Internodal Distance - | Equivalent to marketed products |
| Water Entry Pressure - | Equivalent to marketed products |
| Radial Tensile Strength - | Equivalent to marketed products |
| Longitudinal Tensile Strength - | Equivalent to marketed products |
| Burst Strength - | Equivalent to marketed products |
| Suture Retention Strength (Longitudinal) - | Equivalent to marketed products |
| Suture Retention Strength (Oblique) - | Equivalent to marketed products |
| Suture Hole Elongation - | Equivalent to marketed products |
| Kink Diameter - | Equivalent to marketed products |
| Crush Resistance - | Equivalent to marketed products |
| Burst After Repeated Puncture (12 months) - | Equivalent to marketed products |
| Burst After Repeated Puncture (18 months) - | Equivalent to marketed products |
| Relaxed Internal Diameter - | Equivalent to marketed products |
| Usable Length - | Equivalent to marketed products |
| Nominal Wall Thickness - | Equivalent to marketed products |
- CONCLUSION:** The Meadox Medicals, Inc., Vascular Graft has a level of safety and effectiveness comparable to currently marketed ePTFE Vascular Grafts.