

PREMARKET NOTIFICATION
Meadox
 MEADOX® EXXCEL™ Unwrapped ePTFE Vascular Graft
 Friday, June 21, 1996

MAR 17 1997

K962433

SUMMARY OF SAFETY & EFFECTIVENESS

GENERAL INFO: Sponsor - Meadox Medicals, Inc.
 Contact Person - Susan Eichler-Huston
 Submission Date - June 21, 1996

DEVICE INFO: Generic Name - Expanded PTFE Vascular Graft
 Trade Name - MEADOX® EXXCEL™ ePTFE Vascular Graft
 Classification Name - Vascular Graft Prosthesis (less than 6 mm)
 Vascular Graft Prosthesis (6 mm and greater)

PREDICATE DEVICES:

K-Number	Proprietary Name	Company
Preamendment	IMPRA® Vascular Graft	IMPRA, Inc.
K791810	IMPRA® Vascular Graft	IMPRA, Inc.
K955460	EXXCEL™ ePTFE Graft (6 - 10mm)	Meadox Medicals, Inc.
K960766	EXXCEL™ ePTFE Graft (3 - 5mm)	Meadox Medicals, Inc.

DEVICE DESCRIPTION: The unwrapped version of the MEADOX® EXXCEL™ ePTFE Vascular Graft is comprised of an expanded polytetrafluoroethylene (ePTFE) core tube. Externally supported grafts have a continuous PTFE spiral support coil wound around a portion of the graft.

BIOCOMPATIBILITY: Biocompatibility testing on MEADOX® EXXCEL™ ePTFE Vascular Grafts was performed on single-cycle steam sterilized grafts in accordance with the ISO-10993¹ standard for biological evaluation of medical devices. Carcinogenicity testing was not performed on MEADOX® EXXCEL™ ePTFE Vascular Grafts due to the established nontoxic properties of the graft materials. Prior biocompatibility testing was performed indicates that MEADOX® EXXCEL™ ePTFE Vascular Grafts are safe for their intended use.

Summary of Biocompatibility Testing			
Test Description	ISO 10993	MEADOX® EXXCEL™	Pass or Fail
Cytotoxicity	✓	✓	pass
Sensitization	✓	✓	pass
Irritation or Intracutaneous reactivity	✓	✓	pass
Systemic Toxicity (acute)	✓	✓	pass
Sub-chronic toxicity (sub-acute)	✓	✓	pass
Genotoxicity / Mutagenicity	✓	✓	pass
Implantation	✓	✓	pass
Hemocompatibility (Hemolysis)	✓	✓	pass
Chronic Toxicity	✓	✓	pass
Carcinogenicity	✓		N/A

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 ™ EXXCEL is a trademark of MEADOX MEDICALS, INC. a Division of the Boston Scientific Corporation

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INDICATIONS: The MEADOX® EXXCEL™ 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 MEADOX® EXXCEL™ ePTFE Vascular Grafts are substantially equivalent to the predicate devices identified above.

MANUFACTURING: The MEADOX® EXXCEL™ ePTFE Vascular Graft is produced by heating, stretching and winding an extruded polytetrafluoroethylene tube.

SPECIFICATIONS: Performance specifications of the MEADOX® EXXCEL™ ePTFE Vascular Grafts are substantially equivalent to the range of performance specifications found in the previously identified predicate devices. The following tests were performed to evaluate equivalence to predicate devices:

Test Description	AAMI Standard (reference)	Equivalence pass/fail
Internodal Distance	✓ (8.2.1.3)	pass
Water Entry Pressure	✓ (8.2.4)	pass
Radial Tensile Strength	✓ (8.3.1)	pass
Longitudinal Tensile Strength	✓ (8.3.2)	pass
Burst Strength	✓ (8.3.3.3)	pass
Suture Retention Strength (longitudinal)	✓ (8.8.4.1)	pass
Suture Retention Strength (oblique)	✓ (8.8.4.2)	pass
Suture Hole Elongation	N/A	pass
Kink Diameter	✓ (8.9)	pass
Crush Resistance	N/A	pass
Burst After Repeated Puncture (12 months)	✓ (8.3.4)	pass
Burst After Repeated Puncture (18 months)	✓ (8.3.4)	pass
Relaxed Internal Diameter	✓ (8.5)	pass
Usable Length	✓ (8.4)	pass
Nominal Wall Thickness	✓ (8.7)	pass

CONCLUSION: The MEADOX® EXXCEL™ ePTFE Vascular Graft has a level of safety and effectiveness comparable to currently marketed ePTFE Vascular Grafts.

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