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Section 510(k)

Summary of Safety and Effectiveness Information

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name/Contact

Company: IMPRA, A Subsidiary of C. R. Bard, Inc.
1625 West Third Street
Tempe, Arizona 85281

Contact: Kristi M. Kistner
Manager, Regulatory Affairs
Telephone: (602) 894-9515
Fax: (602) 966-7062

Establishment

Registration Number: 2020394

Device Name

Trade Name: IMPRA ePTFE Arteriovenous Cuffed Graft
Common Name(s): Vascular Graft Prosthesis
Classification Names/Codes: Vascular graft prostheses of less than 6 mm diameter
(74DYF)

Substantially Equivalent Device

IMPRA ePTFE Vascular Graft

Device Description

The IMPRA ePTFE Arteriovenous Cuffed Graft is an expanded polytetrafluoroethylene angioaccess graft [i.e., an IMPRA ePTFE Vascular Graft, the predicate device for this 510(k)] with a modified venous end. The venous end is cuffed, facilitating vessel conformity, a uniform suturing surface, and improved flow through the anastomosis.

The IMPRA ePTFE Arteriovenous Cuffed Graft is made from the same materials as the predicate device, i.e., polytetrafluoroethylene (PTFE), lubricant used as a manufacturing aid, a blue pigment used in the orientation lines, and the external support PTFE beading. These grafts are supplied in the same product configurations as the predicate device (straight, stepped, CenterFlex, and stepped CenterFlex), and are packaged, labeled, and sterilized in the same manner as the predicate device.

Indication for Use

The IMPRA ePTFE Arteriovenous Cuffed Graft is indicated for use as a subcutaneous arteriovenous conduit for blood access. The predicate device, the IMPRA ePTFE Vascular Graft, is indicated for use in blood access, bypass, or reconstruction of arterial blood vessels.

Packaging

The IMPRA ePTFE Arteriovenous Cuffed Graft is packaged in a double tray configuration and placed inside of a box. The trays are made from either PVC or PETG and are sealed with Tyvek lids. After sterilization, the product Directions for Use is applied to the outside of the box and the assembly is shrinkwrapped prior to being released to inventory.

Sterilization/Re-sterilization

The IMPRA ePTFE Arteriovenous Cuffed Graft is sterilized with 100% Ethylene Oxide prior to being placed into inventory for sale. Validation of the sterilization process is performed using the overkill method.

The IMPRA ePTFE Arteriovenous Cuffed Graft is a single use device, intended for single patient use, only. The Directions for Use for both the IMPRA ePTFE Arteriovenous Cuffed Graft and the predicate device, the IMPRA ePTFE Vascular Graft, allow for resterilization of the graft with steam in the event that a package has been inadvertently opened, and the product has not been damaged or contaminated with blood or any foreign material. The resterilization instructions in the Directions for Use have been validated by IMPRA.

Physical Testing

Device testing was performed on the cuffed portion of the IMPRA ePTFE Arteriovenous Cuffed Graft and compared to the results of testing performed on the IMPRA ePTFE Vascular Graft.

The testing was conducted using methods recommended in ANSI/AAMI VP20 - 1994.

Cardiovascular implants - Vascular Prostheses and the 1993 FDA Draft Guidance: Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses. The results of all testing indicated that the IMPRA ePTFE Arteriovenous Cuffed Graft is suitable for use as a subcutaneous arteriovenous conduit for blood access and the anticipated conditions of use imposed on the device. The results demonstrated that the IMPRA ePTFE Arteriovenous Cuffed Graft has been adequately designed to perform in a manner substantially equivalent to that of the predicate device.

Preclinical Testing - Animal Study

A short-term animal study (8 weeks) was conducted to compare intimal hyperplasia formation in IMPRA ePTFE Vascular Grafts and IMPRA ePTFE Arteriovenous Cuffed Grafts in an established sheep model. Grafts were evaluated at implant for handling characteristics (needle penetration difficulty, suture drag, and suture hole bleeding). At explant, grafts and adjacent vessels were photographed and prepared for histology to determine thickness of intimal hyperplasia, degree of luminal narrowing and cellular characterization.

The handling assessment indicated that the IMPRA ePTFE Arteriovenous Cuffed Graft performed better, overall, than the IMPRA ePTFE Vascular Graft. The morphometric analysis of cross sections through the venous ends of the grafts showed that IMPRA ePTFE Arteriovenous Cuffed Grafts had less intimal area and a lower percentage of stenosed area at the venous end than did the IMPRA ePTFE Vascular Grafts. However, the differences between groups were not statistically significant. The morphometric analysis of sections through the toe regions of the grafts

showed that the IMPRA ePTFE Arteriovenous Cuffed Grafts had 50% less average intimal thickness in this region than did the IMPRA ePTFE Vascular Grafts. This difference was statistically significant.

The conclusion of the study was that the results demonstrated that the addition of a distal cuff decreased intimal hyperplasia at the venous end of the graft. This effect could be expected to result in a decreased failure rate and longer graft patency.

Preclinical Testing - Biocompatibility/Toxicity

IMPRA has completed biocompatibility/toxicity testing on IMPRA ePTFE Vascular Grafts, the predicate device for this 510(k), in accordance with the requirements of ISO Standard 10993, FDA Blue Book Memorandum #G87-1, and Good Laboratory Practices. This testing confirms the biocompatibility of IMPRA ePTFE Vascular Grafts. Additional cytotoxicity testing was conducted on IMPRA ePTFE Arteriovenous Cuffed Grafts (per the guidelines in FDA Blue Book Memorandum #G95-1). The test samples evoked no cytotoxic responses.

Clinical Testing

Clinical testing was performed on a device (AVP) that utilized the same cuffed configuration at the venous anastomosis as the IMPRA ePTFE Arteriovenous Cuffed Graft. The IMPRA ePTFE Arteriovenous Cuffed Graft was developed using the AVP graft as a template. The cuff angle is the same for both devices, and the overall cuff length and width for the IMPRA ePTFE Arteriovenous Cuffed Graft were based on data from the inventor of the AVP.

The primary differences between the two devices are the construction and the wall thickness. The IMPRA ePTFE Arteriovenous Cuffed Graft is manufactured from one piece of expanded PTFE, using no sutures or additional materials. The AVP is made using two ePTFE pieces, sutured together to form the cuff. The wall thickness of the cuffed portion of the IMPRA ePTFE Arteriovenous Cuffed Graft is less than the wall thickness of the cuffed portion of the AVP. This difference in wall thickness is due to the proprietary manufacturing process utilized in the manufacture of the IMPRA ePTFE Arteriovenous Cuffed Graft and does not compromise the safety of the device.

The clinical study was designed and conducted by Dr. Hans Scholz, Chief of Vascular Surgery, Queen Elisabeth Hospital, Berlin. Dr. Scholz is the inventor of the AVP. All clinical procedures were performed at the Charite Hospital, Berlin. Between August 1992 to June 1996, 174 AVP grafts constructed from standard 4 mm to 7 mm Stepped IMPRA ePTFE grafts were implanted as straight AV shunts in the upper arm of patients in need of vascular access for hemodialysis. The AVP grafts used in this study were constructed by the investigator intra-operatively. During the same period, fifty (50) conventional 4 mm to 7 mm Stepped IMPRA ePTFE grafts were also implanted in the upper arm in a non-randomized fashion. Patients were entered into this study only if a native A-V fistula could not be constructed in the arm. Patients were excluded only if they had a known hypercoagulability condition, or had arterial hypotension with systolic values below 100 mm Hg.

No anticoagulants were used during this study. Beginning with patient number 101, intra-

operative application of antibiotics (Tarzobac) was instituted as an infection prophylactic.

Observations were recorded at the time of the operation. Follow-up included immediate postoperative development and continued up to the second year after implantation of the prosthesis. Post-operative observations took place at intervals of six months.

Analysis of the results indicated that patient demographics in both groups were comparable with regard to the gender, age, height, weight, mean blood pressure, and number of previous operations.

Life table analysis indicates that the cumulative primary patencies were 88% at 45 months for AVP grafts and 66% at 27 months for the conventional prostheses (control). The mean duration of shunt function was comparable in both groups.

Complications in both groups were comparable except for the number of deaths and the thrombosis rate. The overall thrombosis rates were 5.2% for the AVP group and 16% for the conventional (control) group. There was a 21.8% death rate in the AVP group and a 12% death rate in the conventional group, with the mean time to death in the AVP group longer than the time for the conventional group (23.6 vs. 13.2 months, respectively). The patients that died due to cardiac failure in the AVP group were found to have had significant cardiac and other co-morbidities at the time of graft implantation. Comparison of flow rates between selected patients with AVP and conventional grafts at various follow-up times indicated that the AVP graft did not

increase the flow rates through the shunt. It was concluded that the AVP grafts did not contribute to the deaths of these patients.

The above summary indicates that clinical implantation and use of the AVP graft did not adversely affect the safety (complications) or efficacy (patency) when used as a vascular access graft for hemodialysis. The AVP clinical experience evaluates the performance of the cuffed design and supports the safety of the IMPRA ePTFE Arteriovenous Cuffed Graft.

Equivalence

The IMPRA ePTFE Arteriovenous Cuffed Graft is supplied in the same sizes (internal diameter and usable length) and configurations (Straight, CenterFlex, Stepped, and Stepped CenterFlex grafts in standard wall thickness), and is packaged, labeled, and sterilized in the same manner as the IMPRA ePTFE Vascular Graft to which substantial equivalence is claimed. The uncuffed portion of the IMPRA ePTFE Arteriovenous Cuffed Graft is the IMPRA ePTFE Vascular Graft. The IMPRA ePTFE Arteriovenous Cuffed Graft is made by further processing the predicate device to create a flared or cuffed end on the venous end of the graft. The cuffed portion of the IMPRA ePTFE Arteriovenous Cuffed Graft is the only technological characteristic that differentiates this device from the IMPRA ePTFE Vascular Graft.

Functionally, the cuffing processes produce a flared segment on the largest diameter end of the graft. This flared end is referred to as the cuff and has the same configuration (angle, length, and width) on all graft sizes and product types. The cuffing processes do not affect the microporous

structure of the product, but they do significantly reduce the wall thickness at the cuff. This reduction in wall thickness does not compromise the strength (longitudinal, burst, suture retention) of the IMPRA ePTFE Arteriovenous Cuffed Graft. Also, the handling characteristics (needle penetration, suture drag, suture hole bleeding) of the IMPRA ePTFE Arteriovenous Cuffed Graft were judged to be equivalent or superior to the IMPRA ePTFE Vascular Graft when implanted in eight sheep.

Therefore, it must be concluded that the technological characteristics of this device do not raise any new types of questions of safety or effectiveness. The IMPRA ePTFE Arteriovenous Cuffed Graft has been adequately designed to perform in a manner substantially equivalent to that of the predicate device.

Conclusion

IMPRA ePTFE Arteriovenous Cuffed Grafts and IMPRA ePTFE Vascular Grafts are manufactured in the same ISO 9001:1994 certified facility in Tempe, Arizona. This facility has recently undergone FDA GMP establishment inspections and UK Department of Health inspections. The IMPRA ePTFE Arteriovenous Cuffed Graft utilizes the same validated base graft and secondary processes as the IMPRA ePTFE Vascular Graft. The cuffed portion of the graft is formed with three additional processes after base graft and secondary processes have been completed. These cuffing processes are subject to the same equipment and process qualifications, validations, and quality system requirements as the base graft and secondary processes.

There are no significant differences in design, material, or performance characteristics between the IMPRA ePTFE Arteriovenous Cuffed Graft and the IMPRA ePTFE Vascular Graft that could adversely affect safety or effectiveness. The IMPRA ePTFE Arteriovenous Cuffed Graft is substantially equivalent to the IMPRA ePTFE Vascular Graft.