"I was from the Government and I'm Here to Help!"

FDA Resources to Benefit Your Practice by Helping Assure Safe and Effective Medical Device Use

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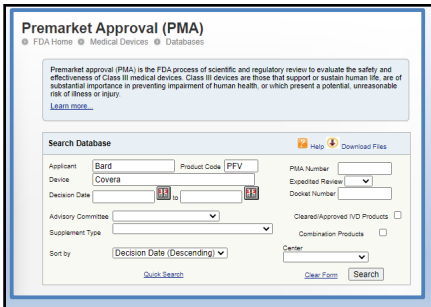
Disclosures

- I was a full time employee of the US FDA until retiring on 9/30/2024
- Current principal, Echelon Development
- No commercial conflicts relative to this presentation

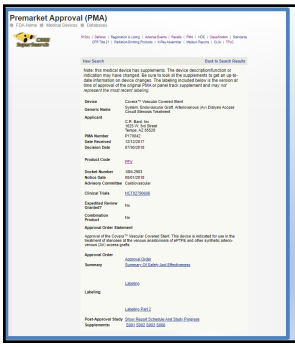
Device Labeling

- Indications for Use
- Adequate Operating Instructions
- Expected Risks / Benefits
- **Contraindications: risks outweigh the benefits**
- **Warnings : death or serious injury**
- **Precautions: minor or moderate injury**



Device Databases:

PMA
De Novo
510(k)



PMA DATABASE LINKS

- Clinical Trials.gov web site
- PMA approval order
- Product labeling
- Post-Approval Study Database
- Summary of Safety and Effectiveness (SSED)

Summary of Safety and Effectiveness Data

The SSED summarizes the key content of the PMA, and includes the

- Device Description,
- Preclinical Evidence, and
- Clinical Evidence, and
- FDA's analysis supporting the reasonable assurance of the safety and effectiveness of the device when used as indicated.

XII. CONCLUSIONS DRAWN FROM CLINICAL STUDY

A. Effectiveness Conclusions

To demonstrate clinically acceptable effectiveness, the primary effectiveness endpoint was evaluated against the rate of Target Lesion Primary Patency (TLPP) at 6 months for standard PTA alone. TLPP at 6 months post-index procedure was evaluated using the Kaplan-Meier analysis and results were 78.7% in the COVERA™ group and 47.9% in the PTA group. The results demonstrated that, with respect to TLPP, the COVERA™ Vascular Covered Stent was superior to the PTA control ($p < 0.001$) for treatment of stenoses in the venous outflow of patients dialyzing with an arteriovenous fistula. The key secondary effectiveness endpoint of TLPP at 12 months was also met. At 12 months, TLPP was 57.5% for COVERA™ treated subjects versus 21.2% in the PTA group.

The significant benefit in TLPP did not carry over to Access Circuit Primary Patency (ACPP). At 6 months, ACPP was 50.7% for COVERA™ treated subjects versus 43.8% in the PTA group. The key secondary effectiveness endpoint for ACCP at 6 months was not met (p-value = 0.0846).

Reintervention data for the two study cohorts at 12 months are tabulated below:

Table 35: Reintervention Data for the two study cohorts

	COVERA™ Group	PTA Group
Total number of access circuit reinterventions	326	242
Total number of target lesion reinterventions	93	193
Total number of reinterventions for new lesions in the access circuit	142	98
Number of subjects requiring access circuit reinterventions	100	102
Number of subjects requiring target lesion reinterventions	57	100
Number of subjects with reinterventions for new lesions in the access circuit	75	49

While the total number of reinterventions for access circuit were similar, there was a considerable reduction in the number of reinterventions for the target lesions after treatment with COVERA™ Vascular Covered Stent compared to PTA alone. However, more reinterventions for new lesions in the access circuit were required in the COVERA™ treated group compared to the PTA alone group. Secondary patency for the COVERA™ treated subjects was 94.3% and for the PTA group was 97.1%.

SSED: Best concise information source on device performance

7

Manufacturer and User Facility Device Experience (MAUDE) Database

FDA Home › Medical Devices › Databases

The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

Learn More

Search Database Help Download Files

Product Problem
Product Class
Event Type — Manufacturer
Model Number — Report Number
Brand Name — Product Code PQK — Summary Report
Exemption Number — UDI-Device Identifier
Date Report Received by FDA *(mm/dd/yyyy)* 1/1/2018 to 1/31/2028 — PMA/510K Number
Go to Simple Search — 10 Records per Report Page — Clear Form — Search

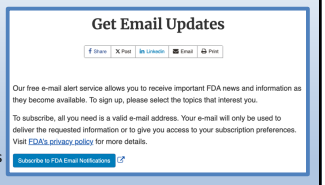
MAUDE DATABASE

8

FDA Communications

The FDA posts **Letters to Health Care Providers** about safety concerns with medical devices used in health care facilities.

Medical Device Safety Communications present FDA's analysis of a current safety issue and provide specific regulatory approaches and clinical recommendations for patient management.



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9

The Long-Term EVAR Assessment and Follow-Up (LEAF) System

- Industry sponsored initiative
- Arose from the 2021 FDA endograft panels that pointed out the need for long term device specific EVAR follow-up.
- Led by Dr. Phil Goodney

LEAF Objectives

Accurately Measure Long-Term Post-EVAR Outcomes:

- **Survival**
- **Reintervention**
- **Late AAA rupture**

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10

LEAF is built on data from the Vascular Implant Surveillance and Interventional Outcomes Network (VQI-VISION) and Kaiser Permanente

PRACTICE MANAGEMENT

Check for updates

The Vascular Implant Surveillance and Interventional Outcomes (VISION) Coordinated Registry Network: An effort to advance evidence evaluation for vascular devices

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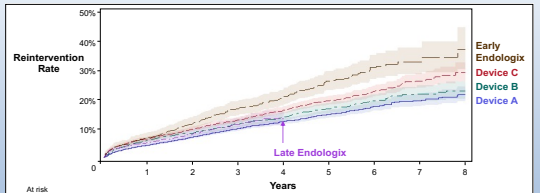
11

VQI-VISION and Kaiser Collaboratively Have Built LEAF for Long-Term EVAR Surveillance



At risk									
Device A	8,310	5,576	3,799	2,602	1,643	995	544	292	163
Device B	6,606	4,609	3,256	2,242	1,455	903	498	241	108
Device C	3,281	2,427	1,865	1,419	1,014	648	363	197	110
Early Endologix	1,044	851	736	612	518	248	127	51	20
Late Endologix	1,972	1,289	781	367	<11				

12

FDA DEVICE RESOURCE LINKS

- PMA Database
- 510(k) Database
- DeNovo Database
- MAUDE Database
- Medical Product Safety Network
- Medical Device Recalls
- 522 Post-market Surveillance Studies Database
- Letters to Health Care Providers
- Safety Communications
- Subscribe to FDA Email Notifications

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13