FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

24 Hour Summary of the Circulatory System Devices Panel Meeting
November 2, 2021

Introduction:

The Circulatory System Devices Panel of the Medical Device Advisory Committee met on November 2, 2021 to discuss and make recommendations on the benefit-risk profile of the Endologix AFX endovascular graft system with regards to the risk of Type III endoleaks. The FDA also requested panel input on the totality of data on AFX devices and whether further actions are necessary.

FDA Questions

QUESTION #1. Totality of Data

Considering the totality of the available information, please discuss the Type III endoleak concern associated with the AFX family of devices, focusing on the currently available AFX product (AFX2):

A. Please discuss the strength of the evidence that the AFX family of devices (and the AFX2 device in particular) is associated with a clinically meaningful increased rate of Type III endoleaks (all Type III endoleaks and Types IIIa and IIIb).

> ***Panel Consensus:*** **The data show a clinically meaningful increased risk of Type III endoleaks associated with the AFX with Strata device. For the AFX2 device, data were insufficient to show that the Type III endoleak risk has been adequately addressed.**

B. Please discuss the effectiveness of the sponsor's mitigation strategies (including device design/manufacturing changes and updated instructions for use) to lower the Type III endoleak risk.

> ***Panel Consensus:*** **The sponsor's mitigation strategies, including labeling updates, did not adequately lower the Type III endoleak risk and failed to identify patients at increased risk.**

C. Considering your responses to Questions 1A and 1B, please discuss additional strategies (such as such as instructions for use or other labeling changes) that could prevent, mitigate, or treat Type III endoleaks that may be associated with the AFX family of devices, particularly the AFX2 device.

> ***Panel Consensus:*** **Patients should be informed of the Type III endoleak risk and the importance of annual follow-up. A shared decision-making process should be included in treatment decisions regarding the AFX2 device.**

QUESTION #2. Benefit-Risk Profile

Please discuss whether the totality of the data (including post-market data) continue to support that the benefits of the currently available AFX2 device outweigh the risks.

> ***Panel Consensus:*** **A majority of panelists did not agree that the benefits outweighed the risk for routine use of AFX2 for treatment of abdominal aortic aneurysms. However, the majority of panelists supported continued availability of the device in selected patient populations and in situations in which alternative treatments are not available. In all patients treated with AFX devices, long-term surveillance is warranted.**

QUESTION #3. Additional Clinical Data

Please discuss whether additional clinical data are needed to further evaluate the safety and effectiveness of the AFX family of devices, particularly the AFX2 device. If you conclude that additional clinical data are needed, please discuss key study elements such as a registry infrastructure, enrollment criteria, clinical and imaging endpoints, and duration of follow-up.

> ***Panel Consensus:*** **Additional clinical data are needed to further evaluate the safety and effectiveness of the AFX family of devices, particularly the currently marketed AFX2 device.**
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> **The Panel recommended expanding analyses from currently available data sources such as the Vascular Quality Initiative (VQI) registry and other analyses using Medicare claims data. They acknowledged the limitations with regards to the delays in data availability, lack of device model identification, and lack of specific data on Type III endoleaks.**
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> **The Panel emphasized the importance of timely data collection and analysis to evaluate Type III endoleak risks associated with the AFX2 device. The Panel recommended patient follow-up to 5 years with some panelists favoring to data beyond 5 years.**
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> **Several panelists recommended collecting clinical outcomes in the selected indications such as patients with small access vessels and occlusive peripheral vascular disease patients; these data would define the safety and effectiveness of the AFX2 in these selected conditions. The Panel also emphasized the importance of collecting patient-centric and quality of life data. Finally, they emphasized the importance of collecting annual computed tomography (CT) imaging data on all AFX patients.**

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